

Celsion CORP  
Form 10-K  
March 13, 2014

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**FORM 10-K**

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**(Mark One)**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2013**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 001-15911**

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**CELSION CORPORATION**

**(Exact Name of Registrant as Specified in Its Charter)**

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**DELAWARE**  
**(State or Other Jurisdiction of Incorporation or Organization)**

**52-1256615**  
**(I.R.S. Employer Identification No.)**

**997 LENOX DRIVE, SUITE 100**

**08648**

**LAWRENCEVILLE, NJ**

**(Address of Principal Executive Offices)**

**(Zip Code)**

**(609) 896-9100**

**Registrant's Telephone Number, Including Area Code**

**Securities registered pursuant to Section 12(b) of the Act:**

**Title of Each Class**

**COMMON STOCK, PAR VALUE \$.01 PER SHARE**

**Name of Each Exchange on Which Registered**

**NASDAQ CAPITAL MARKET**

**Securities registered pursuant to Section 12(g) of the Act:**

**None**

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Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

(Do not check if a smaller reporting company)

Smaller Reporting Company

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No

As of June 28, 2013, the aggregate market value of the common stock held by non-affiliates of the Registrant was approximately \$61,365,512, based on the closing sale price for the Registrant's common stock on that date as reported

by The NASDAQ Capital Market. For purposes of this calculation, shares of common stock held by directors and officers of the Registrant at June 28, 2013 were excluded.

As of March 12, 2014, 17,215,475 shares of the Registrant's common stock were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement to be filed for its 2014 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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**CELSION CORPORATION**

**FORM 10-K**

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## PART I

### ITEM 1. BUSINESS

#### FORWARD-LOOKING STATEMENTS

*Certain of the statements contained in this Annual Report on Form 10-K are forward-looking and constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, from time to time we may publish forward-looking statements relating to such matters as anticipated financial performance, business prospects, technological developments, product pipelines, clinical trials and research and development activities, the adequacy of capital reserves and anticipated operating results and cash expenditures, current and potential collaborations, strategic alternatives and other aspects of our present and future business operations and similar matters that also constitute such forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost, timing and progress of development, preclinical studies, clinical trials and regulatory submissions; our or our collaborator's ability to obtain and maintain regulatory approval of any of our product candidates; possible changes in capital structure, financial condition, future working capital needs and other financial items; changes in approaches to medical treatment; introduction of new products by others; success or failure of our current or future collaboration arrangements, risks and uncertainties associated with possible acquisitions of other technologies, assets or businesses; our ability to obtain additional funds for our operations; our ability to obtain and maintain intellectual property protection for our technologies and product candidates and our ability to operate our business without infringing the intellectual property rights of others; our reliance on third parties to conduct preclinical studies or clinical trials; the rate and degree of market acceptance of any approved product candidates; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities; compliance with listing standards of The NASDAQ Capital Market; and those listed under "Risk Factors" below and elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "expect," "anticipate," "estimate," "plan," "believe," "could," "intend," "predict," "may," "should," "will," "would" and words of similar import regarding the Company's expectations. Forward-looking statements are only predictions. Actual events or results may differ materially. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, you should specifically consider various factors, including the risks outlined under "Risk Factors." The discussion of risks and uncertainties set forth in this Annual Report on Form 10-K is not necessarily a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is in a state of evolution. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors, may cause results to differ materially from those contained in any*

*forward-looking statement. Except as required by law, we assume no obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf for any reason, even if new information becomes available in the future.*

*Unless the context requires otherwise or unless otherwise noted, all references in this Annual Report on Form 10-K to “Celsion” “the Company”, “we”, “us”, or “our” are to Celsion Corporation, a Delaware corporation.*

## **Trademarks**

The Celsion Corporation (“Celsion” or “the Company”) brand and product names, including but not limited to Celsion® or ThermoDox®, contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

## OVERVIEW

Celsion is an oncology drug development company focused on the development of treatments for those suffering with difficult-to-treat forms of cancer. We are working to develop and commercialize more efficient, effective and targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy while minimizing side-effects common to cancer treatments.

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the OPTIMA study) starting in the first half of 2014 and is being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY Study). ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at mild hyperthermia temperatures (greater than 39.5 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

On January 31, 2013, we announced that ThermoDox® in combination with radio frequency ablation (RFA) did not meet the primary endpoint of Progression Free Survival (PFS) for the 701 patient clinical trial (the HEAT Study) in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer. Specifically, we determined, after conferring with the HEAT Study independent Data Monitoring Committee (DMC), that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT study results, we continue to follow patients for overall survival, the secondary endpoint of the HEAT study, on a quarterly basis. We have conducted a comprehensive analysis of the data from the HEAT study to assess the future strategic value of ThermoDox®. As part of this analysis, we are also re-evaluating our product pipeline and research and development priorities. In April 2013, we announced the deferral of expenses associated with the Company's Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases (The ABLATE Study) until such time as the Company finalizes its plans for the continuation of its development program with ThermoDox® in HCC.

The data from the HEAT Study post-hoc analysis suggests that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment. Data from four overall survival sweeps have been conducted since the top line PFS data from the HEAT Study was announced in January 2013, with each showing progressive improvement in statistical significance. In January 2014, we announced that the latest overall survival data from the post-hoc analysis of results from the HEAT Study supports continued clinical development through a prospective pivotal Phase III Study. As reported in January 2014, post-hoc data from the HEAT Study demonstrate that the patient subgroup in the ThermoDox® arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients), experienced a 55% improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495. Median overall survival for this subgroup has not yet been reached. We may choose to end this analysis of overall survival once the median is reached for either or both arms of the study.

Emerging data from the HEAT Study post-hoc analysis has been presented at three scientific and medical conferences in 2013 by key HEAT Study investigators and leading liver cancer experts. The presentations include:

World Conference on Interventional Oncology in May 2013

European Conference on Interventional Oncology in June 2013

International Liver Cancer Association Annual Conference in September 2013

The Company also completed computational modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

On February 24, 2014, we announced that the FDA, after its customary 30 day review period, has provided and allowed, subject to compliance with regulatory standards, clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial (the OPTIMA Study) of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with RFA in primary liver cancer, also known as hepatocellular carcinoma (HCC). The OPTIMA Study trial design is based on the comprehensive analysis of data from the HEAT study, which, as described above, demonstrated that treatment with ThermoDox resulted in a 55 percent improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment. The Company expects to launch the study in the first half of 2014. The OPTIMA Study is designed with extensive input from globally recognized HCC researchers and clinicians and after formal written consultation with FDA. The OPTIMA Study is expected to enroll approximately 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific, and will evaluate ThermoDox® in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival, and the secondary endpoint for the trial is PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

In addition, the Company recently met with the China State Food and Drug Administration (CHINA FDA) to discuss the OPTIMA Phase III trial including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, we are submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe and will meet with the European Medicines Agency (EMA) in the first half of 2014.

In April 2013, we engaged Cantor Fitzgerald & Co. to conduct a comprehensive review of merger and acquisition opportunities with the goal of identifying novel products with high potential, or companies, to acquire. Strategic alternatives the Company may pursue could include, but are not limited to, continuing its current operating plan, partnering or other collaboration agreements, acquisition of another company's business or assets, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. As demonstrated by the HEAT Study results in January 2013, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, results of operations, financial condition and market value.

In 2007, the Company sold its medical device franchise to Boston Scientific Corporation for net aggregate payments of \$43 million, receiving \$13 million in 2007 and \$15 million in each of 2008 and 2009. Since this divestiture, we have dedicated our efforts and resources to the development and commercialization of cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. To support our research and development, we have raised gross proceeds of approximately \$95 million in equity financings and warrant and option exercises in the years 2009 through 2013. In January 2014, the Company raised net proceeds of \$14 million through an equity financing and, including its cash, investments and interest receivable totaling \$43.1 million at the end 2013, has \$57 million to fund its operations in 2014 and beyond. During 2012 and 2013, the Company secured two credit facilities totaling \$20 million collectively, one of which has been fully repaid, and currently has up to \$15 million remaining under the surviving facility.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co., Ltd. (the Yakult Agreement) under which we granted Yakult an exclusive right to commercialize and market ThermoDox® for the Japanese market. We received a \$2.5 million upfront licensing fee and may receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. Under the Yakult Agreement, we will receive double-digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur and we also will be the exclusive supplier of ThermoDox® to Yakult. In January 2011, we amended the Yakult Agreement to provide for up to \$4.0 million in an accelerated partial payment to us of a future drug approval milestone which included \$2.0 million paid to us upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the

HEAT study. In consideration of these accelerated milestone payments from Yakult, we agreed to reduce future drug approval milestone payments by approximately forty percent (40%). All other milestone payments are unaffected.

On May 6, 2012, we entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Hisun will be responsible for providing all of the technical and regulatory support services for the manufacture of ThermoDox® in the China territory and we will repay Hisun the related development costs and fees, which we expect to be approximately \$2.0 million in total, commencing on the successful completion of three registrational batches of ThermoDox®. On January 18, 2013, we broadened our relationship with Hisun by entering into a technology development contract, pursuant to which Hisun paid us a non-refundable research and development fee of \$5.0 million to support our development of ThermoDox® and we will provide research data and other technical support in relation to a regulatory filing by Hisun in China for approval of ThermoDox®. Following our announcement of the HEAT study results on January 31, 2013, we and Hisun have agreed that the technology development contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate the next steps in relation to ThermoDox®, which include the continued subgroup analysis of the Chinese cohort of patients in the HEAT Study for primary liver cancer and other activities to further the development of ThermoDox® for the China territory.

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described in "Part I, Item 1A. Risk Factors" in this Annual Report on Form 10-K.

#### **THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)**

Liposomes are manufactured submicroscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring lipids. Conventional liposomes have been designed and manufactured to carry drugs and increase residence time, thus allowing the drugs to remain in the bloodstream for extended periods of time before they are removed from the body. However, the current existing liposomal formulations of cancer drugs and liposomal cancer drugs under development do not provide for the immediate release of the drug and the direct targeting of organ specific tumors, two important characteristics that are required for improving the efficacy of cancer drugs such as doxorubicin. A team of research scientists at Duke University developed a heat-sensitive liposome which rapidly changes its structure when heated to a threshold minimum temperature of 39.5° to 42° Celsius. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue. Through a perpetual, world-wide, exclusive development and commercialization license from Duke University, Celsion has licensed novel, heat-activated liposomal technology that is differentiated from other liposomes through its unique low heat-activated release of encapsulated chemotherapeutic agents.

We intend to use several available focused-heat technologies, such as radio frequency ablation (RFA), microwave energy and high intensity focused ultrasound (HIFU), to activate the release of drugs from our novel heat-sensitive liposomes.

***THERMODOX® IN RELATION TO PRIMARY LIVER CANCER***

**Liver Cancer Overview**

Primary liver cancer (hepatocellular carcinoma or HCC) is one of the most common and deadliest forms of cancer worldwide. It ranks as the fifth most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 28,000 cases per year in the United States, approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 750,000 cases per year. HCC has the fastest rate of growth of all cancers and is projected to be the most prevalent form of cancer by 2020. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S. and Europe and hepatitis B in Asia).



At an early stage, the standard first line treatment for liver cancer is surgical resection of the tumor. Up to 80% of patients are ineligible for surgery or transplantation at time of diagnosis as early stage liver cancer generally has few symptoms and when finally detected the tumor frequently is too large for surgery. There are few alternative treatments, since radiation therapy and chemotherapy are largely ineffective. For tumors generally up to 5 centimeters in diameter, RFA has emerged as the standard of care treatment which directly destroys the tumor tissue through the application of high temperatures by a probe inserted into the core of the tumor. Local recurrence rates after RFA directly correlates to the size of the tumor. For tumors 3 cm or smaller in diameter the recurrence rate has been reported to be 10 – 20%; however, for tumors greater than 3 cm, local recurrence rates of 40% or higher have been observed.

### **Celsion's Approach**

While RFA uses extremely high temperatures (greater than 80° Celsius) to ablate the tumor, it may fail to treat micro-metastases in the outer margins of the ablation zone because temperatures in the periphery may not be high enough to destroy the cancer cells. Celsion's ThermoDox® treatment approach is designed to utilize the ability of RFA devices to ablate the center of the tumor while simultaneously thermally activating the ThermoDox® liposome to release its encapsulated doxorubicin to kill remaining viable cancer cells throughout the heated region, including the tumor ablation margins. This novel treatment approach is intended to deliver the drug directly to those cancer cells that survive RFA. This approach will also increase the delivery of the doxorubicin at the desired tumor site while potentially reducing drug exposure distant to the tumor site.

The data from the Company's 701-patient HEAT Study post-hoc analysis suggests that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment. We continue to follow patients in the HEAT Study to the secondary endpoint, overall survival (OS). Data from four overall survival sweeps have been conducted since the top line PFS data from the HEAT Study was announced in January 2013, with each showing progressive improvement in statistical significance. In January 2014, we announced that the latest overall survival data from its post-hoc analysis of results from the HEAT Study supports continued clinical development through a prospective pivotal Phase III Study. As reported in January 2014, post-hoc data from the Company's HEAT Study demonstrate that the patient subgroup in the ThermoDox arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients), experienced a 55% improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495.

### **Phase I Clinical Trial - Primary Liver Cancer**

In the second quarter of 2007, we completed our first Phase I single dose escalation clinical trial that investigated ThermoDox® in combination with RFA for the treatment of primary and metastatic liver cancer. The study was carried out at the National Cancer Institute (NCI), which is part of the National Institutes of Health (NIH) and Queen Mary Hospital in Hong Kong.

In 2007 we initiated a second Phase I dose escalation study designed to investigate simplification of the current RFA/ThermoDox® treatment regimen including a single vial formulation of ThermoDox® designed for commercial distribution. The study also permitted multiple dosing in liver cancer patients. This clinical trial was completed in 2008.

#### **701 Patient Global Clinical Trial - Primary Liver Cancer (The HEAT Study)**

The HEAT Study for ThermoDox®, in combination with RFA, was conducted in patients with primary liver cancer under a Special Protocol Assessment agreed to with the FDA. The Special Protocol Assessment (SPA) agreed to with the FDA specified PFS as the HEAT Study's primary endpoint. We scheduled a meeting with the HEAT Study independent DMC on January 30, 2013 in order to conduct an analysis of the HEAT Study's PFS endpoint. Following review by the DMC, on January 31, 2013, we announced that ThermoDox® in combination with RFA did not meet the HEAT Study's primary endpoint of PFS. Specifically, we determined, after conferring with the DMC, that the HEAT Study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval in the population chosen for the HEAT Study. The HEAT Study was designed to show a 33 percent improvement in PFS with 80 percent power and a p-value = 0.05. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events.

As provided for in the SPA, we continue to follow the patients enrolled in the HEAT study to the secondary endpoint of Overall Survival (OS). We have evaluated data from four reviews of overall survival since the announcement of the HEAT study's primary endpoint result. We also completed computational modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

In January 2014, we announced that the latest overall survival data from the post-hoc analysis of results from the HEAT study support continued clinical development of ThermoDox® through a prospective pivotal Phase III study, subject to regulatory review and agreement. The post-hoc data demonstrated that the patient subgroup in the ThermoDox® arm whose RFA procedure lasted longer than 45 minutes, which represents 285 patients or 63 percent of single lesion patients, experienced a 55 percent improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495. Median overall survival for this subgroup has not yet been reached. The post-hoc data suggest that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment.

In January 2014, the Company announced that the latest overall survival data from its post-hoc analysis of results from the HEAT Study supports continued clinical development through a prospective pivotal Phase III Study. The data from the HEAT Study post-hoc analysis suggests that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment. The Company continues to follow patients in the HEAT Study to the secondary endpoint of OS. Data from four OS sweeps have been conducted since the top line PFS data from the HEAT Study was announced in January 2013, with each showing progressive improvement in statistical significance. We may choose to end the analysis of OS once the median is reached for either or both arms of the HEAT Study.

We will continue with partnerships, such as our arrangement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) described below, to the extent feasible. In addition, we have assessed our product pipeline and research and development priorities. As we evaluate strategic alternatives, we will need to consider a number of factors, including investment in, or acquisition of, complementary businesses, technologies or products, possible capital raising transactions, partnering opportunities and working capital requirements. We expect that the strength of our balance sheet will afford us the opportunity to evaluate our future development plans. However, as demonstrated by the HEAT Study results on PFS announced on January 31, 2013, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition and market value.

### **Phase III Global Clinical Trial - Primary Liver Cancer (The OPTIMA Study)**

Based on the overall survival data from the post-hoc analysis of results from HEAT Study, we submitted our proposed pivotal Phase III clinical protocol for the FDA review in the fourth quarter of 2013. On February 24, 2014, we announced that the FDA, after its customary 30 day review period, has provided and allowed, subject to compliance with regulatory standards, clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial (the OPTIMA Study) of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with radio frequency ablation (RFA) in primary liver cancer. The OPTIMA Study trial design is based on a comprehensive analysis of data from the Company's Phase III HEAT Study, which demonstrated that treatment with ThermoDox resulted in a 55% improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment. The Company expects to launch the study in the first half of 2014.

The Phase III OPTIMA Study is designed with extensive input from globally recognized HCC researchers and clinicians, and after formal consultation with FDA. The OPTIMA Study is expected to enroll 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific and will evaluate ThermoDox in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. As reported in January 2014, post-hoc data from the Company's HEAT Study demonstrate that the patient subgroup in the ThermoDox® arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients), experienced a 55% improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495. The primary endpoint for the trial is overall survival, and the secondary endpoint for the trial is PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

In addition, the Company recently met with the China FDA to discuss, among other items, the Phase III OPTIMA Study, including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, the Company is submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe for the OPTIMA Study and will meet with the EMA in the first half of 2014.

### ***THERMODOX® IN RELATION TO CANCERS OTHER THAN PRIMARY LIVER CANCER***

In June 2012, we announced a collaboration with the University of Oxford to begin an early phase clinical study of ThermoDox® plus HIFU in the treatment of metastatic liver cancer. The trial, which is supported by the National Institute for Health Research Oxford Biomedical Research Centre, will be carried out as a multidisciplinary collaboration between us, the Oxford University Institute of Biomedical Engineering and the Oxford University Hospitals NHS Trust. This early phase clinical study is being finalized and will require approval from a local ethics committee. Enrollment of the first patient in this clinical study is targeted for 2014.

In collaboration with the Focused Ultrasound Foundation, we are sponsoring preclinical studies designed to explore the use of ThermoDox® in combination with MR-guided HIFU for the treatment of pancreatic cancer. The studies are being conducted at the University of Washington (UW) School of Medicine. The UW research includes animal models to confirm the ability of HIFU to target concentrations of doxorubicin in proprietary pancreatic cancer cell lines and in vivo studies to assess the response to these tumors treated using ThermoDox® with and without HIFU-induced hyperthermia. We believe that these collaborations are providing important new device technologies such as HIFU to activate our low heat sensitive liposomal technology in difficult-to-treat cancers.

### **Recurrent Chest Wall (RCW) Breast Cancer Overview**

Breast cancer is the most common malignancy in women in both the United States and the world. Despite a variety of therapeutic approaches, up to 40% of the estimated 95,000 patients in the United States undergoing a mastectomy as their primary treatment will develop locally recurrent RCW breast cancer. There is currently no effective chemotherapeutic standard of care for RCW breast cancer and as a result, many of these patients will die within two years of the recurrence. Patients with RCW breast cancer suffer from disfiguring tumors and other symptoms including pain, foul-smelling wounds, and a very visual reminder of tumor progression.

### **Celsion's Approach**

We have been actively seeking a targeted localized treatment for breast cancer using ThermoDox® in conjunction with localized microwave hyperthermia to treat RCW breast cancer. Studies at Duke University and other centers have indicated that heat may improve the therapeutic action of non-temperature sensitive liposomal doxorubicin formulations in advanced loco-regional breast cancer. Our liposomal encapsulated doxorubicin is released by heat generated from an external microwave tissue hyperthermia device that is placed on a woman's chest. The microwave hyperthermia heats the target to a temperature adequate to activate ThermoDox® but not to ablate the tissue like RFA. Upon heating to 39.5° to 42° C, a significant concentration of doxorubicin is released directly to the tumor. As in our liver cancer program, we use a commercially available thermotherapy device to heat the target tissue and activate ThermoDox® at the desired target site.

Microwave hyperthermia as a separate standalone treatment has been found to have the ability to kill breast cancer cells. Because breast cancer cells have higher water content than surrounding normal cells, the tumor is heated to a greater extent than normal breast tissue and is selectively destroyed. Thus heating cancer cells with a microwave device for sixty minutes at 43°C has been found to be tumoricidal. We expect that the combination of microwave hyperthermia and ThermoDox® will be more efficacious than microwave hyperthermia alone or treatment with existing non-heat activated liposomal formulations.

#### **Breast Cancer Clinical Phase I/II Clinical Trial - The DIGNITY Study**

In 2009, the Company commenced an open label, dose-escalating ThermoDox® Phase I/Phase II clinical trial for patients with RCW breast cancer – (the DIGNITY study). The DIGNITY study is designed to establish a safe therapeutic dose in Phase I, and in Phase II to demonstrate local control, including complete and partial responses, and stable disease as its primary endpoint. The DIGNITY study is also planned to evaluate kinetics in ThermoDox® produced from more than one manufacturing site.

The Company completed enrollment of the Phase I portion of the study in 2010 and an independent Data Safety Monitoring Board declared 50mg/m<sup>2</sup> to be the Phase II dose. The Phase II portion of the DIGNITY study protocol has been reviewed by the FDA and enrollment commenced in the first quarter of 2013. The trial will enroll 20 patients at five clinical sites in the United States and is evaluating ThermoDox® in combination with mild hyperthermia.

Duke University conducted a Phase I dose escalating ThermoDox® study in patients with RCW breast cancer and has presented preliminary results from the 16 enrolled patients that characterize the safety of the drug in RCW patients and the feasibility of ThermoDox® administration in these patients. In December 2013, we announced combined clinical data from our DIGNITY study and the Duke University sponsored Phase I trial of ThermoDox® plus hyperthermia in RCW breast cancer. The two similarly designed Phase I studies enrolled patients with highly resistant tumors found on the chest wall and who had progressed on previous therapy including chemotherapy, radiation therapy and hormone therapy. ThermoDox® in combination with mild hyperthermia was evaluated in these patients in up to six cycles. Both studies employed an open label 3+3 dose escalation study design to determine the Maximum Tolerated Dose, evaluate safety and determine early effects of ThermoDox® in combination with mild hyperthermia. There were 29 patients treated in the two trials, including 11 patients in the DIGNITY study and 18 patients in the Duke study. Of the 29 patients, 23 were eligible for evaluation of efficacy. A local response rate of over 60 percent was reported in 14 of the 23 evaluable patients with five complete responses and nine partial responses.

In February 2014, we announced positive interim data from the ongoing open-label Phase II DIGNITY study. Based on the data available to date, a local response rate of approximately 80 percent has been observed in the five evaluable patients with refractory disease, notably two complete responses, two partial responses and one patient with stable disease. These data are consistent with the previously reported positive Phase I data in RCW breast cancer.

## **PRODUCT FEASIBILITY**

We developed a stable heat activated liposomal formulation of docetaxel and evaluated the liposomal docetaxel formulation in animal studies that demonstrated a statistically significant tumor inhibition effect when compared both to free docetaxel and a non-heat sensitive formulation. We will continue to evaluate this formulation following a successful clinical program utilizing ThermoDox®. In addition, the Company has developed a third stable heat activated liposomal formulation. This drug encapsulates carboplatin and in early studies has shown favorable release characteristics and formulation stability.

## **BUSINESS STRATEGY**

An element of our business strategy has been to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. We may also evaluate licensing cancer products from third parties

for cancer treatments to expand our current product pipeline. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. We may also consider and evaluate strategic alternatives, including investment in, or acquisition of, complementary businesses, technologies or products. As demonstrated by the HEAT Study results, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results is extremely difficult to predict. The success or failure of any preclinical development and clinical trial can have a disproportionately positive or negative impact on our results of operations, financial condition, prospects and market value.

As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product if one of our product candidates receives regulatory approval for marketing, if at all. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research and development activities, preclinical studies and clinical trials, or whether we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.



## RESEARCH AND DEVELOPMENT EXPENDITURES

We are engaged in a limited amount of research and development in our own facilities and have sponsored research programs in partnership with various research institutions, including the National Cancer Institute and Duke University. We are currently, with minimal cash expenditures, sponsoring clinical and pre-clinical research at the University of Utrecht, Brigham and Women's Hospital and the University of Washington. The majority of the spending in research and development is for the funding of ThermoDox® clinical trials. Research and development expenses were approximately \$9.4 million, \$15.8 million and \$19.9 million for the years ended December 31, 2013, 2012 and 2011, respectively. See *Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operation* for additional information regarding expenditures related to our research and development programs.

## GOVERNMENT REGULATION

### *Regulation in the United States*

#### **Research and Development**

Our research and development activities, pre-clinical tests and clinical trials are subject to extensive regulation by the FDA as would the manufacturing, marketing and labeling of our products, if any. The Federal Food, Drug and Cosmetic Act, the Public Health Service Act and the regulations promulgated by the FDA govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising, promotion, import and export of our products.

Under these statutes, our heat-activated liposomes will be regulated as a new drug. The steps ordinarily required before such products can be marketed in the U.S. include (a) pre-clinical and clinical studies; (b) the submission to the FDA of an application for, or approval, as an Investigational New Drug application (IND), which must become effective before human clinical trials may commence; (c) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; (d) the submission to the FDA of a New Drug Application (NDA); and (e) FDA approval of the application, including approval of all product labeling.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies, to assess the potential safety and efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practice. The results of pre-clinical tests are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical

trials. Submission of an IND will not necessarily result in FDA authorization to commence clinical trials, and the absence of FDA objection to an IND does not necessarily mean that the FDA will ultimately approve an NDA or that a product candidate otherwise will come to market.

Clinical trials involve the administration of therapy to humans under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with good clinical practices under protocols submitted to the FDA as part of an IND. Also, each clinical trial must be approved and conducted under the auspices of an internal review board (IRB), and with patient informed consent. An IRB will consider, among other things, ethical factors and the safety of human subjects and the possible liability of the institution conducting the clinical trials.

Clinical trials are typically conducted in two or three sequential phases, but the phases may overlap. Phase I clinical trials involve the initial introduction of the therapy to a small number of subjects. Phase II trials are generally larger trials conducted in the target population. Phase II studies may serve as the pivotal trials, providing the demonstration of safety and effectiveness required for approval. However, the FDA may require additional, post-market trials as a condition of approval. In the case of drugs and biological products, Phase II clinical trials generally are conducted in a target patient population to gather evidence about the pharmacokinetics, safety and biological or clinical efficacy of the drug for specific indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. When a drug or biological compound has shown evidence of efficacy and an acceptable safety profile in Phase II evaluations, Phase III clinical trials are undertaken to serve as the pivotal trials to demonstrate clinical efficacy and safety in an expanded patient population.

There can be no assurance that any of our clinical trials will be completed successfully within any specified time period or at all. On January 31, 2013, we announced that ThermoDox® in combination with RFA did not meet the primary endpoint of the HEAT study in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer. Specifically, we determined, after conferring with the DMC, that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval in the population chosen for the HEAT study.

On February 24, 2014, we announced that the FDA, after its customary 30 day review period, has provided and allowed, subject to compliance with regulatory standards, clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial (the OPTIMA Study) of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with RFA in primary liver cancer, also known as hepatocellular carcinoma (HCC). The OPTIMA Study trial design is based on a comprehensive analysis of data from the Company's Phase III HEAT Study, which demonstrated that treatment with ThermoDox resulted in a 55% improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment. Celsion expects to launch the study in the first half of 2014.

The Phase III OPTIMA Study is designed with extensive input from globally recognized HCC researchers and clinicians, and after formal consultation with FDA. The OPTIMA Study is expected to enroll 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific and will evaluate ThermoDox in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is OS. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

In addition, the Company recently met with the CHINA FDA to discuss the Phase III OPTIMA Study, including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, the Company is submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe for the OPTIMA Study and will meet with the EMA in the first half of 2014.

Either the FDA or we may suspend clinical trials at any time, if the FDA, our iDMC, or we conclude that clinical subjects are being exposed to an unacceptable health risk or for other reasons. The FDA inspects and reviews clinical trial sites, informed consent forms, data from the clinical trial sites (including case report forms and record keeping procedures) and the performance of the protocols by clinical trial personnel to determine compliance with good clinical practices. The FDA also examines whether there was bias in the conduct of clinical trials. The conduct of clinical trials is complex and difficult, especially in pivotal Phase II or Phase III trials. There can be no assurance that the design or the performance of the pivotal clinical trial protocols or any of our current or future product candidates will be successful.

The results of pre-clinical studies and clinical trials, if successful, are submitted in an application for FDA approval to market the drug or biological product for a specified use. The testing and approval process requires substantial time and effort, and there can be no assurance that any approval will be granted for any product at any time, according to any schedule, or at all. The FDA may refuse to accept or approve an application if it believes that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy. Moreover, if regulatory approval is granted, the approval will be limited to specific indications. There can be no assurance that any of our current product candidates will receive regulatory approvals for marketing or, if approved, that approval will be for any or all of the indications that we request.

In 2009, the FDA granted orphan drug designation for ThermoDox® for the treatment of HCC. Orphan drug designation entitles the Company to seven years of market exclusivity following FDA approval, if any, FDA assistance in clinical trial design, a reduction in FDA user fees, U.S. tax credits related to development expenses as well as the opportunity to apply for funding from the U.S. government to defray the costs of clinical trial expenses.

## **Post-Approval Requirements**

After receipt of necessary regulatory approvals, if any, for initial manufacturing and sale of our product candidates, our contract manufacturing facilities and products are subject to ongoing review and periodic inspection. Each U.S. drug manufacturing establishment must be registered with the FDA. Manufacturing establishments in the U.S. and abroad are subject to inspections by the FDA and must comply with current good manufacturing practices. In order to ensure full technical compliance with such practices, manufacturers must expend funds, time and effort in the areas of production and quality control. In addition, the FDA may impose post-approval requirements on us, including the requirement that we conduct specified post-marketing studies.

## **Inspections**

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter only is to be issued for violations of “regulatory significance” for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

## **Recalls**

The FDA has the authority to require the recall of our products in the event of material deficiencies or defects in manufacture. A governmentally mandated recall, or a voluntary recall by us, could result from a number of events or factors, including component failures, manufacturing errors, instability of product or defects in labeling.

## **Other FDA Regulations**

We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures.

Labeling and promotional activities are also regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

### *Regulation Outside of the U.S.*

In addition to regulations in the U.S., we will be subject to regulations of other countries governing any clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the U.S. before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union and China, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and is optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

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In 2011, the European Commission granted orphan drug designation for ThermoDox® for the treatment of HCC in Europe. As established by the EMA, orphan drug designation provides for scientific advice and regulatory assistance from the EMA, direct access to centralized marketing authorization and certain financial incentives, such as reduction of fees associated with pre-authorization inspections and marketing authorization application fees. The orphan drug designation in Europe also provides 10 years of market exclusivity subsequent to product approval.

## **PRODUCT LIABILITY AND INSURANCE**

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident, and if we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim out of our own limited resources.

## **COMPETITION**

Competition in the discovery and development of new methods for treating and preventing disease is intense. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies both in the U.S. and abroad. We face significant competition from organizations pursuing the same or similar technologies used by us in our drug discovery efforts and from organizations developing pharmaceuticals that are competitive with our product candidates.

Most of our competitors, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, most of these organizations, either alone or together with their collaborators, have significantly greater experience than we do in developing products, undertaking preclinical testing and clinical trials, obtaining FDA and other regulatory approvals of products, and manufacturing and marketing products. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated among our competitors. These companies, as well as academic institutions, governmental agencies, and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical and biotechnology field also depends on the status of our collaborations and on the continuing availability of capital to us.

**ThermoDox®**

Although there are many drugs and devices marketed and under development for the treatment of cancer, the Company is not aware of any other heat activated drug delivery product either being marketed or in human clinical development.

## **LICENSES, PATENTS AND TRADEMARKS**

In 1999, the Company entered into a license agreement with Duke University under which we received exclusive rights, subject to certain exceptions, to commercialize and use Duke's thermo-liposome technology. In relation to these liposome patents licensed from Duke University, we have filed two additional patents related to the formulation and use of liposomes. We have also licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In 2003, our obligations under the license agreement with Duke University with respect to the testing and regulatory milestones and other licensed technology performance deadlines were eliminated in exchange for a payment of shares of our common stock. The license agreement continues to be subject to agreements to pay a royalty based upon future sales. In conjunction with the patent holder, we have filed international applications for a certain number of the United States patents.

Our rights under the license agreement with Duke University extend for the longer of 20 years or the end of any term for which any relevant patents are issued by the United States Patent and Trademark Office. Currently, the Company has rights to Duke's patent for its thermo-liposome technology in the United States, which expires in 2018, and to future patents received by Duke in Canada, Europe, Japan and Australia, where it has patent applications have been granted. The European grant provides coverage in the European Community. For this technology, the Company's license rights are worldwide, including the United States, Canada, certain European countries, Australia, Hong Kong, and Japan.



On February 5, 2013, Celsion announced that its proprietary patent application, "Method of Storing Nanoparticle Formulations," had been allowed in China and granted in South Korea and Australia. Celsion holds an exclusive license agreement with Duke University for its temperature-sensitive liposome technology that covers the ThermoDox® formulation. Celsion's newly issued patents pertain specifically to methods of storing stabilized, temperature-sensitive liposomal formulations and will assist in the protection of global rights. These patents will extend the overall term of the ThermoDox® patent portfolio to 2026. The patents in these three countries are the first in this family, which includes pending applications in the U.S., Europe and additional key commercial geographies in Asia. This extended patent runway to 2026 allows for the evaluation of future development activities for ThermoDox® and Celsion's heat-sensitive liposome technology platform.

In addition to the rights available to us under completed or pending license agreements, we rely on our proprietary know-how and experience in the development and use of heat for medical therapies, which we seek to protect, in part, through proprietary information agreements with employees, consultants and others. There can be no assurance that these proprietary information agreements will not be breached, that we will have adequate remedies for any breach, or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company's proprietary technology. Please refer to Item 1A, Risk Factors, including, but not limited to, "We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition." Similarly, we cannot guarantee that technology rights licensed to us by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide us with adequate protection. Please refer to Item 1A, Risk Factors, including, but not limited to, "Our business depends on licensing agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products."

## **EMPLOYEES**

As of March 12, 2014, we employed 13 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

## **COMPANY INFORMATION**

Celsion was founded in 1982 and is a Delaware corporation. Our principal executive offices are located at 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648. Our telephone number is (609) 896-9100. The Company's website is [www.celsion.com](http://www.celsion.com). The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report on Form 10-K.

## AVAILABLE INFORMATION

We make available free of charge through our website, [www.celsion.com](http://www.celsion.com), our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (the "SEC"). In addition, our website includes other items related to corporate governance matters, including, among other things, our corporate governance principles, charters of various committees of the Board of Directors, and our code of business conduct and ethics applicable to all employees, officers and directors. We intend to disclose on our internet website any amendments to or waivers from our code of business conduct and ethics as well as any amendments to its corporate governance principles or the charters of various committees of the Board of Directors. Copies of these documents may be obtained, free of charge, from our website. In addition, copies of these documents will be made available free of charge upon written request. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file periodic and other reports electronically with the Securities and Exchange Commission. The address of that site is [www.sec.gov](http://www.sec.gov). The information available on or through our website is not a part of this Annual Report on Form 10-K and should not be relied upon.

## LIQUIDITY AND CAPITAL RESOURCES

During 2013, we issued a total of 5.3 million shares of common stock, including shares of common stock issued upon conversion of the 15,000.00422 shares of Series A 0% convertible preferred stock, in the following equity transactions for an aggregate \$31.6 million in gross proceeds. On October 28, 2013, we effected a 4.5-to-1 reverse split of our common stock. Unless otherwise expressly stated, the share and per share data in this section and elsewhere in this Annual Report on Form 10-K have been adjusted to reflect the reverse stock split.

On February 1, 2013, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may offer and sell, from time to time through “at-the-market” offerings, shares of our common stock having an aggregate offering price of up to \$25.0 million. From February 1, 2013 through February 25, 2013, we sold and issued an aggregate of 1,195,923 shares of common stock under such agreement for approximately \$6.8 million in aggregate gross proceeds.

On February 22, 2013, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which we sold, in a registered direct offering, an aggregate of 15,000.00422 shares of our Series A 0% convertible preferred stock and warrants to purchase up to 1,341,382 shares of common stock, for an aggregate purchase price of approximately \$15.0 million in gross proceeds. All of the shares of Series A 0% convertible preferred stock have been converted into 2,682,764 shares of common stock.

On May 30, 2013, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which we sold, in a registered direct offering, an aggregate of 1,392,109 shares of our common stock for an aggregate purchase price of approximately \$9.8 million in gross proceeds.

During 2013, we received gross proceeds of approximately \$0.4 million from the exercise of warrants and common stock options to purchase 30,499 shares of common stock.

In addition, the Company entered into a loan agreement on November 25, 2013 with Hercules Technology Growth Capital, Inc. (Hercules), pursuant to which the Company may borrow a secured term loan of up to \$20 million in multiple tranches (the Hercules Credit Agreement). The Company drew the first tranche of \$5 million at the closing under the Hercules Credit Agreement on November 25, 2013 and may request, subject to Hercules’ consent in its sole discretion, an additional \$15 million in up to three advances with each advance in a minimum amount of \$5 million, unless otherwise agreed upon by the Company and Hercules, before June 30, 2014 unless extended upon Hercules’ consent. The Company used approximately \$4 million of the first tranche to repay the outstanding obligations under a loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation. The Company anticipates that it will use any additional funding up to \$15 million as provided under the agreement for working capital or in support of its previously announced strategic acquisition initiative, which is designed to identify new technologies and clinical stage products for its development pipeline. The loan bears interest at a floating per annum rate equal to the greater of (i) 11.25 percent and (ii) the sum of 11.25 per cent plus the prime rate minus 3.25 per cent. Payments under

the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

We believe that our cash and investment resources of \$43.1 million on hand at December 31, 2013, as well as the \$13.8 million of net proceeds the Company received in the first quarter of 2014 from the January 15, 2014 common stock offering, are sufficient to fund operations through 2016. However, our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. To complete the development and commercialization of our products, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot give assurance that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, preferred stock, convertible debt or other convertible or exercisable securities, which financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock.

## RECENT EVENTS

### January 2014 Registered Direct Offering

On January 15, 2014, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 3,603,604 shares of its common stock, par value \$0.01 per share, and warrants to purchase up to 1,801,802 shares of Common Stock, for an aggregate purchase price of approximately \$15 million.

On February 24, 2014, we announced that the FDA, after its customary 30 day review period, has provided and allowed, subject to compliance with regulatory standards, clearance for our planned pivotal, double-blind, placebo-controlled Phase III trial (the OPTIMA Study) of ThermoDox® in combination with RFA in primary liver cancer (HCC). The OPTIMA Study trial design is based on the comprehensive analysis of data from the Phase III HEAT study, which demonstrated that treatment with ThermoDox® resulted in a 55 percent improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment. The Company expects to launch the study in the first half of 2014. The OPTIMA study is designed with extensive input from globally recognized HCC researchers and clinicians and after formal consultation with FDA. The OPTIMA study is expected to enroll 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific, and will evaluate ThermoDox® in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival, and the secondary endpoint for the trial is PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

In addition, the Company recently met with the China State Food and Drug Administration (CHINA FDA) to discuss the OPTIMA Phase III trial, including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, the Company is submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe and meet with the European Medicines Agency (EMA) in the first half of 2014.

## ITEM 1A. RISK FACTORS

*We are providing the following cautionary discussion of risk factors, uncertainties and assumptions that we believe are relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ significantly from expected or historical results and our forward-looking statements. We note these factors for investors as permitted by Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), and Section 27A of the Securities Act of 1933, as amended (Securities Act). You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties that may impact our business. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise.*

### RISKS RELATED TO OUR BUSINESS

**We have a history of significant losses from operations and expect to continue to incur significant losses for the foreseeable future.**

Since our inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$169 million at December 31, 2013. For the year ended December 31, 2011, 2012 and 2013, we incurred a net loss of \$23.2 million, \$26.6 million and \$8.3 million, respectively. We currently have no product revenue and do not expect to generate any product revenue for the foreseeable future. Because we are committed to continuing our product research, development, clinical trial and commercialization programs, we will continue to incur significant operating losses unless and until we complete the development of ThermoDox® and other new products and these products have been clinically tested, approved by the U.S. Food and Drug Administration (FDA) and successfully marketed. The amount of future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third party alternatives for any approved product and raising sufficient funds to finance business activities. If we or our collaborators are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Our lead drug candidate failed to meet its primary endpoint in the Phase III HEAT study.**

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation (RFA) failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as the HEAT study. We have not completed our final analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox®. We expect to launch a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA study, in the first half of 2014. The trial design of the OPTIMA study is based on the overall survival data from the post-hoc analysis of results from the HEAT study. ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies.

Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT study. Drug development is very risky. It will take us several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates. The failure of one or more of our drug candidates or development programs could have a material adverse effect on our business, financial condition and results of operations.

**If we do not obtain or maintain FDA and foreign regulatory approvals for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, we will be unable to sell those products and our business, results of operations and financial condition will be negatively affected.**

To obtain regulatory approvals from the FDA and foreign regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials or the FDA and/or foreign regulatory agencies may require us to perform additional trials beyond those we planned. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

**We do not expect to generate revenue for the foreseeable future.**

We have devoted our resources to developing a new generation of products and will not be able to market these products until we have completed clinical trials and obtain all necessary governmental approvals. Our lead product candidate, ThermoDox®, is still in various stages of development and trials and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint of progression free survival, we continue to follow the patients enrolled in the Heat study to the secondary endpoint, overall survival. Based on the overall survival data from the post-hoc analysis of results from the HEAT study, we plan to launch a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA study, in the first half of 2014. ThermoDox® is currently also being evaluated in Phase II clinical trials and other preclinical studies. We do not expect to realize any revenue from product sales in the next several years, if at all. Accordingly, our revenue sources are, and will remain, extremely limited until our product candidates are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our product candidates will be successfully tested, approved by the FDA or foreign regulatory agency or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

**We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.**



As of December 31, 2013, we had approximately \$ 43.1 million in cash, cash equivalents and short-term investments. We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages. For example, ThermoDox® is being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies, and we expect to launch the OPTIMA study in the first half of 2014. We will continue to conduct additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox® and are performing sub-group analysis of the Chinese cohort of patients in the HEAT study and other activities for further development of ThermoDox® for mainland China, Hong Kong and Macau. To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we are unable to obtain additional capital on a timely basis or on acceptable terms, we may be required to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

**We may not successfully engage in strategic transactions, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expense and present significant distractions to our management.**

We may consider strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products, out- or in-licensing product candidates or technologies or entering into a business combination with another company. Any strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

**Our business depends on license agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products.**

Our success will depend, in a substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. We have entered into license agreements with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke's thermo-sensitive liposome technology. The Duke University license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet

by certain deadlines. Additionally, we have a joint research agreement with Philips Healthcare, a division of Royal Philips Electronics, to evaluate the combination of Philips' high intensity focused ultrasound (HIFU) with ThermoDox® to determine the potential of this combination to treat a broad range of cancers. If we breach any provisions of the license and research agreements, we may our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We may be required to alter any of our potential products or processes, or enter into a license and pay licensing fees to a third party or cease certain activities. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and commercializing the product. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of others' claimed proprietary rights.

**We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.**

We rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot assure you that these agreements are adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

**Our products may infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.**

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we currently are not involved in any material litigation involving patents, a third party patent holder may assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for any losses they may sustain. We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms, or may not be available at all. Any modification to include a non-infringing technology may not be possible or if possible may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

**We rely on third parties to conduct all of our clinical trials. If these third parties are unable to carry out their contractual duties in a manner that is consistent with our expectations, comply with budgets and other financial obligations or meet expected deadlines, we may not receive certain development milestone payments or be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.**

We rely, and expect to continue to rely, on third-party clinical investigators, clinical research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor our clinical trials. Because we do not have the ability to conduct our own clinical trials, we must rely on the efforts of others and have limited control over, and cannot predict accurately, the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not expect to significantly increase our personnel in the foreseeable future and may continue to rely on third parties to conduct all of our future clinical trials. If we cannot contract with acceptable third parties on commercially reasonable terms or at all, if these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become significantly more expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires clinical trials to be conducted in accordance with good clinical practices, including for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Because we rely on third party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.**

We rely on third party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies. We do not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by FDA and foreign regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

**Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.**

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are all subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenues or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety

and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates. Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes, or those of our vendors and suppliers, are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of “regulatory significance” for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with the FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA’s review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the Company.

We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures.

Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

Many states in which we do or may do business, or in which our products may be sold, if at all, impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

**Legislative and regulatory changes affecting the healthcare industry could adversely affect our business.**

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last few years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect healthcare reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainty remains regarding proposed significant reforms to the U.S. health care system.

**The success of our products may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.**



Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

**Our products may not achieve sufficient acceptance by the medical community to sustain our business.**

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any of our drug candidates may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, which would have an adverse effect on our business, financial condition and results of operations.

**The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.**

It is very difficult to predict the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the revenue potential for such drug candidate and would adversely affect our business, financial condition and results of operations.

**We have no internal sales or marketing capability. If we are unable to create sales, marketing and distribution capabilities or enter into alliances with others possessing such capabilities to perform these functions, we will not be able to commercialize our products successfully.**

We currently have no sales, marketing or distribution capabilities. We intend to market our products, if and when such products are approved for commercialization by the FDA and foreign regulatory agencies, either directly or through other strategic alliances and distribution arrangements with third parties. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products, we will need to establish and maintain partnership arrangements, and there can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on acceptable terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

**Technologies for the treatment of cancer are subject to rapid change, and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.**

Various methods for treating cancer currently are, and in the future are expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

**We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our products and business.**

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our products and businesses. During our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry “key man” insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

**Our success will depend in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.**

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our business effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

**We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.**

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

**We may be subject to significant product liability claims and litigation.**

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident and \$10 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a severe adverse effect on our business. Whether or not we are ultimately successful in any product liability litigation, such litigation would harm the business by diverting the attention and resources of our management, consuming substantial amounts of our financial resources and by damaging our reputation. Additionally, we may not be able to maintain our product liability insurance at an acceptable cost, if at all.

**Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.**

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical data or data from any clinical trial involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could

be delayed.

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## RISKS RELATED TO OUR SECURITIES

**The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.**

The trading price for our common stock has been, and we expect it to continue to be, volatile. Our January 31, 2013 announcement that the HEAT study failed to meet its primary endpoint has resulted in significant volatility and a steep decline in the price of our common stock, a level of decline that could result in securities litigation. Plaintiffs' securities litigation firms have publicly announced that they are investigating potential securities fraud claims that they may wish to make against us. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock as reported on The NASDAQ Capital Market had a high price of \$42.12 and a low price of \$3.47 in the 52-week period ended December 31, 2013, as adjusted to reflect the 4.5-to-1 reverse split of our common stock effected as of October 28, 2013, and a high price of \$4.57 and a low price of \$3.54 from January 2, 2014 through March 12, 2014. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

results of preclinical and clinical studies of our product candidates or those of our competitors;

regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;

actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;

introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;

announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;

fluctuations in our quarterly operating results or the operating results of our competitors;

variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

failure of our products to achieve or maintain market acceptance or commercial success;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

actual or expected sales of our common stock by our stockholders; and

the trading volume of our common stock.





In addition, the stock markets, in general, The NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

**Future sales of our common stock in the public market could cause our stock price to fall.**

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of March 12, 2014, we had 17,215,475 shares of common stock outstanding, all of which shares, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

**Our stockholders may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.**

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock. Our stockholders may experience significant dilution as a result of future equity offerings or issuance. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of March 12, 2014, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 5,069,814 shares of common stock issuable upon exercise of warrants outstanding, 1,186,662 options to purchase shares of our common stock and restricted stock awards outstanding, and 4,450 shares of common stock reserved for future issuance under our stock incentive plans. Under the Controlled Equity Offering<sup>SM</sup> Sales Agreement entered into with Cantor Fitzgerald & Co. on February 1, 2013, we may offer and sell, from time to time through "at-the-market" offerings, up to an aggregate of \$25 million of shares of our common stock and we only sold \$6.8 million under the agreement as of March 12, 2014.

**We may be unable to maintain compliance with NASDAQ Marketplace Rules which could cause our common stock to be delisted from The NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.**

Our common stock is currently listed on The NASDAQ Capital Market. To maintain the listing of our common stock on The NASDAQ Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and stockholders' equity of at least \$2.5 million; or (ii) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and a total market value of listed securities of at least \$35 million. As of March 12, 2014, the closing sale price of our common stock was \$3.94, the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors and 10% or more stockholders) was approximately \$67 million and the total market value of our listed securities was approximately \$68 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of December 31, 2013, we had stockholders' equity of \$31.5 million.

On October 28, 2013, we effected a 4.5-to-1 reverse stock split of our common stock primarily for purposes of increasing the market price of our common stock, among others, and our common stock started to trade on the post-split basis on October 29, 2013. Other companies have found that the increased stock prices resulting from reverse splits tend to diminish over time unless supported by positive developments in the business. The closing price of our common stock as reported on The NASDAQ Capital Market has declined from \$5.14 on October 29, 2013 to \$3.94 on March 12, 2014.

If the closing bid price of our common stock is below \$1.00 per share or the total market value of our publicly held shares of common stock is below \$35 million for 30 consecutive business days, we could be subject to delisting from The NASDAQ Capital Market. If our common stock is delisted, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules regarding “penny stock,” which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to investors in penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher priced stock, would further limit the ability and willingness of investors to trade in our common stock. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

**The adverse capital and credit market conditions could affect our liquidity.**

Adverse capital and credit market conditions could affect our ability to meet liquidity needs, as well as our access to capital and cost of capital. The capital and credit markets have experienced extreme volatility and disruption in recent years. Our results of operations, financial condition, cash flows and capital position could be materially adversely affected by continued disruptions in the capital and credit markets.

**Our ability to use net operating losses to offset future taxable income are subject to certain limitations.**

We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. During 2013, 2012 and 2011 the Company performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit its ability to utilize certain net operating loss and tax credit carry forwards. The Company determined that it experienced an ownership change, as defined by Section 382, in connection with certain common stock offerings on July 25, 2011, February 5, 2013 and on June 3, 2013. As a result, the utilization of the Company's federal tax net operating loss carry forwards generated prior to the ownership changes is limited. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

**We have never paid cash dividends on our common stock in the past and do not anticipate paying cash dividends on our common stock in the foreseeable future.**

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future for holders of our common stock.

**Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control.**

Our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of “blank check” preferred stock. This preferred stock may be issued by our board of directors on such terms as it determines, without further stockholder approval. Therefore, our board of directors may issue such preferred stock on terms unfavorable to a potential bidder in the event that our board of directors opposes a merger or acquisition. In addition, our classified board of directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on our board of directors. Certain other provisions of our bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

In 2011, the Company executed a lease with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for six months rent free, with the first monthly rent payment of approximately \$23,000 due in April 2012. Also, as required by the lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The lease stipulated standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the Lease Term has expired. In connection with the \$50,000 reduction of the standby letter of credit in April 2013, the Company reduced the escrow deposit by \$50,000.

We believe our existing facility is suitable and adequate to conduct our business.

**ITEM 3. LEGAL PROCEEDINGS**

We are not currently a party to any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

**PART II****ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS  
5. AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Price for Our Common Stock**

Our common stock trades on The NASDAQ Capital Market under the symbol "CLSN". The following table sets forth the high and low reported closing sale prices for the periods indicated as adjusted to reflect the 4.5-to-1 reverse split of our common stock effected on October 28, 2013. The quotations set forth below do not include retail markups, markdowns or commissions.

	<b>High</b>	<b>Low</b>
<b>YEAR ENDED DECEMBER 31, 2013</b>		
First Quarter (January 1 – March 31, 2013)	\$ 42.12	\$ 4.37
Second Quarter (April 1 – June 30, 2013)	\$ 8.42	\$ 3.47
Third Quarter (July 1 – September 30, 2013)	\$ 6.39	\$ 4.91
Fourth Quarter (October 1 – December 31, 2013)	\$ 5.72	\$ 3.55
<b>YEAR ENDED DECEMBER 31, 2012</b>		
First Quarter (January 1 – March 31, 2012)	\$ 9.99	\$ 7.38
Second Quarter (April 1 – June 30, 2012)	\$ 14.09	\$ 7.92
Third Quarter (July 1 – September 30, 2012)	\$ 26.55	\$ 12.83
Fourth Quarter (October 1 – December 31, 2012)	\$ 39.74	\$ 19.35
<b>YEAR ENDED DECEMBER 31, 2011</b>		
First Quarter (January 1 – March 31, 2011)	\$ 13.37	\$ 9.81
Second Quarter (April 1 – June 30, 2011)	\$ 15.17	\$ 9.72
Third Quarter (July 1 – September 30, 2011)	\$ 19.04	\$ 11.25
Fourth Quarter (October 1 – December 31, 2011)	\$ 16.52	\$ 7.61

On March 12, 2014, the last reported sale price for our Common Stock on the NASDAQ Capital Market was \$3.94. As of March 12, 2014, there were approximately 21,000 stockholders of record of our Common Stock.

## **Performance Graph**

The following graph compares the percentage change in the cumulative return to the stockholders of our common stock during the five year period ended December 31, 2013 with the cumulative return the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the same periods.

The graph assumes that \$100 was invested on December 31, 2008 in our common stock or an index, and that all dividends were reinvested. We have not declared nor paid any dividends on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

## **Dividend Policy**

We have never declared or paid and have no present intention to pay cash dividends on our Common Stock in the foreseeable future. We intend to retain any earnings for use in our business operations.

## **Securities Authorized For Issuance Under Equity Compensation Plans**

See “Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Equity Compensation Plan Information.”

### **Unregistered Shares Of Equity Securities**

All unregistered shares of equity securities have been previously reported by the Company in its Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

### **Issuer Purchases of Equity Securities**

None.



**ITEM 6. SELECTED FINANCIAL DATA**

The selected financial data set forth below is not necessarily indicative of results of future operations and should be read together with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the financial statements and related notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K to fully understand factors that may affect the comparability of the information presented below. All shares and per share data have been adjusted to reflect the 4.5-to-1 reverse split of our common stock effected as of October 28, 2013.

<b>Statement of operations data:</b> (in thousands, except per share data)	<b>Year Ended December 31,</b>				
	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>
Licensing revenue	\$500	\$-	\$2,000	\$-	\$-
Research and development expense	9,364	15,770	19,864	14,714	13,681
General and administrative expense	6,547	6,373	5,155	4,923	3,327
Total operating expense	15,911	22,143	25,019	19,637	17,008
Operating loss	(15,411)	(22,143)	(23,019)	(19,637)	(17,008)
Other income (loss)	7,160	(4,426)	(204)	819	1,006
Net loss	(8,251)	(26,569)	(23,223)	(18,818)	(16,002)
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	(4,602)				
Net loss attributable to common shareholders	\$(12,853)	\$(26,569)	\$(23,223)	\$(18,818)	\$(16,002)
Net loss attributable to common shareholders per common share - basic and diluted	\$(0.95)	\$(3.44)	\$(5.00)	\$(6.84)	\$(6.44)
Weighted average shares used in computing net loss available to common shareholders per common share	13,541	7,731	4,648	2,750	2,368
<b>Balance sheet data:</b> (in thousands)	<b>As of December 31</b>				
	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>
Cash and cash equivalents	\$5,719	\$14,991	\$20,145	\$1,139	\$6,923
Investment securities, available for sale (including interest receivable on investments)	37,368	8,104	10,401	396	5,695
Working capital (deficit)	39,091	18,644	25,356	(4,769)	10,369
Total assets	45,671	25,359	32,649	2,525	14,805
Common stock warrant liability	3	4,284	166	248	822
Non current liabilities	9,476	8,392	303	305	1,018
Total liabilities	14,147	13,397	6,456	7,101	4,769

Total stockholders' equity (deficit)	31,524	11,962	26,194	(4,576)	10,036
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## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussions should be read in conjunction with our financial statements and related notes thereto included in this Annual Report on Form 10-K. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under Part I, Item 1A – Risk Factors appearing in this Annual Report on Form 10-K and factors described in other cautionary statements, cautionary language and risk factors set forth in other documents that we file with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

### **Overview**

Celsion is an oncology drug development company focused on the development of treatments for those suffering with difficult-to-treat forms of cancer. We are working to develop and commercialize more efficient, effective and targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy while minimizing side-effects common to cancer treatments.

### **Significant Events**

#### *ThermoDox®*

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the OPTIMA study) starting in the first half of 2014 and is being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY Study). ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at mild hyperthermia temperatures (greater than 39.5 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

#### *Primary Liver Cancer*

On January 31, 2013, we announced that ThermoDox® in combination with radio frequency ablation (RFA) did not meet the primary endpoint of Progression Free Survival (PFS) of the 701 patient clinical trial (the HEAT Study) in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer. Specifically, we determined, after conferring with the HEAT Study independent Data Monitoring Committee (DMC), that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT study results, we continue to follow patients for overall survival, the secondary endpoint of the HEAT study, on a quarterly basis. We have conducted a comprehensive analysis of the data from the HEAT study to assess the future strategic value of ThermoDox®. As part of this analysis, we are also re-evaluating our product pipeline and research and development priorities. In April 2013, we announced the deferral of expenses associated with the Company's Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases (The ABLATE Study) until such time as the Company finalizes its plans for the continuation of its development program with ThermoDox® in HCC.

The data from the HEAT Study post-hoc analysis suggests that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment. Data from four overall survival sweeps have been conducted since the top line PFS data from the HEAT Study was announced in January 2013, with each showing progressive improvement in statistical significance. In January 2014, we announced that the latest overall survival data from its post-hoc analysis of results from the HEAT Study supports continued clinical development through a prospective pivotal Phase III Study. As reported in January 2014, post-hoc data from the HEAT Study demonstrate that the patient subgroup in the ThermoDox arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients), experienced a 55% improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495.

Emerging data from the HEAT Study post-hoc analysis has been presented at three scientific and medical conferences in 2013 by key HEAT Study investigators and leading liver cancer experts. The presentations include:

World Conference on Interventional Oncology in May 2013

European Conference on Interventional Oncology in June 2013

International Liver Cancer Association Annual Conference in September 2013

The Company also completed computational modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

On February 24, 2014, we announced that the FDA, after its customary 30 day review period, has provided and allowed, subject to compliance with regulatory standards, clearance for our planned pivotal, double-blind, placebo-controlled Phase III trial (the OPTIMA Study) of ThermoDox® in combination with RFA in primary liver cancer (HCC). The OPTIMA Study trial design is based on the comprehensive analysis of data from the HEAT study, which, as described above, demonstrated that treatment with ThermoDox resulted in a 55 percent improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment. The Company expects to launch the study in the first half of 2014. The OPTIMA study is designed with extensive input from globally recognized HCC researchers and clinicians and after formal consultation with FDA. The OPTIMA study is expected to enroll 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific, and will evaluate ThermoDox® in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival, and the secondary endpoint for the trial is PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

In addition, the Company recently met with the China State Food and Drug Administration (CHINA FDA) to discuss the OPTIMA Phase III trial including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, we are submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe and will meet with the European Medicines Agency (EMA) in the first half of 2014.

#### Technology Development Agreements

On May 6, 2012, we entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Hisun will be responsible for providing all of the technical and regulatory support services for the manufacture of ThermoDox® in the China territory and we will repay Hisun the related development costs and fees, which we expect to be approximately \$2.0 million in total, commencing on the successful completion of three registrational batches of ThermoDox®. On January 18, 2013, we broadened our relationship with Hisun by entering into a technology development contract, pursuant to which Hisun paid us a non-refundable research and development fee of \$5.0 million to support our development of ThermoDox® and we will provide research data and other technical support in relation to a regulatory filing by Hisun in China for approval of ThermoDox®. Following our announcement of the HEAT study results on January 31, 2013, we and Hisun have agreed that the technology development contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate the next steps in relation to ThermoDox®, which include the continued subgroup analysis of the Chinese cohort of patients in the HEAT Study for primary liver cancer and other activities to further the development of ThermoDox® for the China territory.

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialized approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described in "Part I, Item 1A. Risk Factors" in this Annual Report on Form 10-K.

#### *Cancers Other Than Primary Liver Cancer*

In June 2012, we announced a collaboration with the University of Oxford to begin an early phase clinical study of ThermoDox® plus HIFU in the treatment of metastatic liver cancer. The trial, which is supported by the National Institute for Health Research Oxford Biomedical Research Centre, will be carried out as a multidisciplinary collaboration between us, the Oxford University Institute of Biomedical Engineering and the Oxford University Hospitals NHS Trust. This early phase clinical study is being finalized and will require approval from a local ethics committee. Enrollment of the first patient in this clinical study is targeted for 2014.

We are also working with the Focused Ultrasound Foundation in preclinical studies designed to explore the use of ThermoDox® in combination with MR-guided HIFU for the treatment of pancreatic cancer. The studies are being conducted at the University of Washington (UW) School of Medicine. The UW research is expected to include animal models to confirm the ability of HIFU to target high concentrations of doxorubicin in proprietary pancreatic cancer cell lines and in vivo studies to assess the response to these tumors treated using ThermoDox® with and without HIFU-induced hyperthermia. We believe that these collaborations are just the beginning for combining important device technologies such as HIFU with our low heat activated liposomal technology.

We are engaged in a limited amount of research and development in our own facilities and have sponsored research programs in partnership with various research institutions, including the National Cancer Institute and Duke University. We are currently, with minimal cash expenditures, sponsoring clinical and pre-clinical research at the

University of Utrecht, Brigham and Women's Hospital and the Washington University.

In addition to the collaborations outlined above, we have one ongoing clinical study, a Phase II study of ThermoDox® in combination with hyperthermia for the treatment of recurrent chest wall (RCW) breast cancer (the DIGNITY study). In April 2013, as part of our comprehensive analysis of the data from the HEAT study, we decided to defer the Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases (the ABLATE study) until such time after we finalize our plans for the continuation of its development program with ThermoDox® in primary liver cancer.

Cantor Fitzgerald & Co.

In April 2013, we engaged Cantor Fitzgerald & Co. to conduct a comprehensive review of merger and acquisition opportunities with the goal of identifying novel products with high potential, or companies, for Celsion to acquire. Strategic alternatives we may pursue could include, but are not limited to, continuing its current operating plan, partnering or other collaboration agreements, acquisition of another company's business or assets, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. As demonstrated by the HEAT Study results in January 2013, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition and market value.



Reverse Stock Split

On October 28, 2013, the Company effected a reverse stock split of our common stock at an exchange ratio of 4.5-to-1 and set the number of authorized shares of common stock outstanding immediately after the split at 75 million shares. As a result of the reverse stock split, every four and a half shares of common stock outstanding immediately prior to the effectiveness of the reverse stock split were combined and converted into one share of common stock immediately thereafter without any change in the per share par value. The Company's common stock started to trade on the post-split basis at the commencement of trading on October 29, 2013 under a new CUSIP number 15117N404 with the same ticker symbol, CLSN. Unless otherwise expressly stated, the share and per share data in this section and elsewhere in this Annual Report on Form 10-K have been adjusted to reflect the reverse stock split.

Equity and Debt Financings

During 2013, we issued 5.3 million shares of common stock, including shares of common stock issued upon conversion of the 15,000.00422 shares of Series A 0% convertible preferred stock, in the following equity transactions for an aggregate \$31.6 million in gross proceeds. On October 28, 2013, we effected a 4.5-to-1 reverse split of our common stock.

On February 1, 2013, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may offer and sell, from time to time through "at-the-market" offerings, shares of our common stock having an aggregate offering price of up to \$25.0 million. From February 1, 2013 through February 25, 2013, we sold and issued an aggregate of 1,195,923 shares of common stock under such agreement for approximately \$6.8 million in aggregate gross proceeds.

On February 22, 2013, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which we sold, in a registered direct offering, an aggregate of 15,000.00422 shares of our Series A 0% convertible preferred stock and warrants to purchase up to 1,341,382 shares of common stock, for an aggregate purchase price of approximately \$15.0 million in gross proceeds. All of the shares of Series A 0% convertible preferred stock have been converted into 2,682,764 shares of common stock.

On May 30, 2013, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which we sold, in a registered direct offering, an aggregate of 1,392,109 shares of our common stock for an aggregate purchase price of approximately \$9.8 million in gross proceeds.

During 2013, we received gross proceeds of approximately \$0.4 million from the exercise of warrants and common stock options to purchase 30,499 shares of common stock.

In addition, the Company entered into a loan agreement on November 25, 2013 with Hercules Technology Growth Capital, Inc. (Hercules), pursuant to which the Company may borrow a secured term loan of up to \$20 million in multiple tranches (the Hercules Credit Agreement). The Company drew the first tranche of \$5 million at the closing under the Hercules Credit Agreement on November 25, 2013 and may request, subject to Hercules' consent in its sole discretion, an additional \$15 million in up to three advances with each advance in a minimum amount of \$5 million, unless otherwise agreed upon by the Company and Hercules, before June 30, 2014 unless extended upon Hercules' consent. The Company used approximately \$4 million of the first tranche to repay the outstanding obligations under a loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation. The Company anticipates that it will use any additional funding up to \$15 million as provided under the agreement for working capital or in support of its previously announced strategic acquisition initiative, which is designed to identify new technologies and clinical stage products for its development pipeline. The loan bears an interest at a floating per annum rate equal to the greater of (i) 11.25 percent and (ii) the sum of 11.25 per cent plus the prime rate minus 3.25 per cent. Payments under the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

On January 15, 2014, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 3,603,604 shares of its common stock, par value \$0.01 per share, and warrants to purchase up to 1,801,802 shares of Common Stock, for an aggregate purchase price of approximately \$15 million.

We believe that our cash and investment resources of \$43.1 million on hand at December 31, 2013, as well as the \$13.8 million of net proceeds the Company collectively received in the first quarter of 2014 from the January 15, 2014 offering, are sufficient to fund operations through 2016. However, our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. To complete the development and commercialization of our products, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot give assurance that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, preferred stock, convertible debt or other convertible or exercisable securities, which financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. Please refer to Item IA, Risk Factors, including, but not limited to, *“We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.”*

### **Critical Accounting Policies and Estimates**

Our financial statements, which appear at Item 7 to this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the United States, which require that we make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 1 to our financial statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

#### *Stock-Based Compensation*

We follow the provisions of ASC topic 718 “Compensation” which requires the expense recognition over a service period for the fair value of share based compensation awards, such as stock options, restricted stock and performance based shares. This standard allows us to establish modeling assumptions as to expected stock price volatility, option terms, forfeiture and dividend rates, which directly impact estimated fair value as determined. Our practice is to utilize reasonable and supportable assumptions which are reviewed with our board of directors and its appropriate committee.

#### *Common Stock Offering*

Prior to the closing of the Common Stock Offering on June 3, 2013, there were an insufficient number of authorized shares to complete the transaction. The investors in the Common Stock Offering also held warrants to purchase common stock of the Company which were issued in connection with previous offerings. Concurrent with the closing of the Common Stock Offering, the institutional investors agreed to waive their rights to exercise these warrants to purchase 1,398,816 shares of common stock of the Company (the "Waived Warrants") until the Company has obtained stockholders' approval to increase the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock. At the Company's 2013 Annual Meeting of Stockholders held on July 19, 2013, the Company's stockholders voted to approve the proposal to grant discretionary authority to the Board of Directors to amend the Certificate of Incorporation of the Company, as amended, to effect, at any time on or prior to the date of the 2014 Annual Meeting of Stockholders, a reverse stock split at an exchange ratio within the specified range and to set the number of authorized shares effective immediately after the reverse stock split at 75 million shares. On October 28, 2013, the Company effected a 4.5-to-1 reverse stock split of its common stock.

The warrants described above were originally recorded as equity at the fair value on the date of issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the Waived Warrants were required to be liability classified immediately after the closing of the Common Stock Offering on June 3, 2013 because there were an insufficient number of common shares authorized to permit the full exercise of the warrants. Therefore on June 3, 2013, the Company reclassified the fair value of the Waived Warrants totaling approximately \$9.1 million from equity to a liability. The Waived Warrants were required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings until such time as there were a sufficient number of common shares authorized to permit the full exercise of the warrants (see Note 11). In connection with the Reverse Stock Split as more fully described below, these warrants were valued as of October 28, 2013, and the Company reclassified the fair value of the Waived Warrants totaling approximately \$5.3 million from a liability to equity.

We review our financial reporting and disclosure practices and accounting policies on an ongoing basis to ensure that our financial reporting and disclosure system provides accurate and transparent information relative to the current economic and business environment. As part of the process, the Company reviews the selection, application and communication of critical accounting policies and financial disclosures. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires that our management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We review our estimates and the methods by which they are determined on an ongoing basis. However, actual results could differ from our estimates.

## **Results of Operations**

### ***Comparison of Fiscal Year Ended December 31, 2013 and Fiscal Year Ended December 31, 2012.***

#### **Licensing Revenue**

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will continue to be amortized over the 10 year term of the agreement, therefore we recorded deferred revenue of \$500,000 in 2013. We had no licensing revenue in 2012 and we do not expect to generate any licensing revenue in 2014 other than deferred revenue of \$500,000 to be recorded in relation to the technology development contract with Hisun.

#### **Research and Development Expenses**

Research and development (R&D) expenses decreased by \$6.4 million from \$15.8 million in 2012 to \$9.4 million in 2013. Costs associated with the HEAT Study decreased to \$3.7 million in 2013 compared to \$7.7 million in 2012 primarily due to reduced costs associated with the HEAT Study after the data results were announced on January 31, 2013. Costs associated with our recurrent chest wall breast cancer clinical trial (the DIGNITY Study) remained relatively unchanged at \$0.4 million in 2013 compared to 2012. As a result of our decision to delay our colorectal liver metastases trial (the ABLATE Study) following the announcement of the HEAT Study results, the related costs were insignificant in 2013 compared to \$0.2 million in 2012. Other R&D costs related to preclinical operations and regulatory operations decreased to \$1.0 million in 2013 compared to \$2.0 million in 2012. Costs associated with the production of ThermoDox® decreased to \$2.8 million in 2013 compared to \$4.0 million the same period of 2012.

In April 2013, the Company has implemented a restructuring program to lower its operating costs to conserve capital to ensure that our costs are adequately aligned with our resources and business strategy. The program included elimination of approximately one-third of Celsion's workforce and the deferral of expenses associated with the ABLATE Study.

As we expect to initiate the OPTIMA Study in the first half of 2014 and as we continue to evaluate ThermoDox® in the DIGNITY Study, we expect research and development costs to increase in 2014 compared to 2013. Our expenditures on current and future preclinical development programs and clinical trials are subject to numerous uncertainties and risks associated with timing, cost and progress of such development programs and clinical trials, including those uncertainties and risks discussed in Part I, Item 1A "Risk Factors" in this Annual Report on Form 10-K.

General and Administrative Expenses

General and administrative expenses increased slightly to \$6.5 million in 2013 compared to \$6.4 million in 2012. This increase is largely the result of an increase in professional fees in 2013 and severance costs (\$0.2 million in 2013) related to the April 2013 restructuring program as discussed above compared to the same period of 2012.

Change in Common Stock Warrant Liability

A warrant liability was incurred as a result of warrants we issued in a public offering in September 2009. The liability associated with these warrants is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. For 2013, we recorded a non-cash benefit of \$4.3 million based on the change in the fair value of the warrants compared to a non-cash charge of \$4.1 million in the same period of 2012.

In connection with the Common Stock Offering in the second quarter of 2013, the investors in the offering agreed to waive their rights to exercise the warrants to purchase 1,398,816 shares of common stock of the Company until the Company had effected a reverse stock split and increased the number of its authorized shares of common stock. During the second quarter of 2013, the Company reclassified the fair value of these warrants totaling \$9.1 million from equity to a liability on the date of the closing of the offering on June 3, 2013. Prior to the offering the warrants described above were originally recorded as equity at the fair value on the date of their issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, these warrants were required to be classified as liabilities immediately after the closing of the common stock offering on June 3, 2013 because there were an insufficient number of common shares authorized to permit the full exercise of the warrants if they were exercised. Therefore, these warrants are required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings. In connection with the reverse stock split the Company effected on October 28, 2013, these warrants were valued as of October 28, 2013, and the Company reclassified the fair value of the Waived Warrants totaling approximately \$5.3 million from a liability to equity. The change in the fair value of the warrants which were waived from the time they were liability classified to the time they were equity reclassified resulted in a non-cash benefit of \$3.8 million in 2013.

Collectively, the Company recorded a non-cash benefit totaling \$8.1 million in 2013 compared to recording a non-cash charge of \$4.1 million in 2012.

Investment income and interest expense

Interest expense in 2013 was \$0.9 million compared to \$0.4 million in 2012. The Company entered into a \$5 million loan facility in June 2012. The Company repaid this loan facility in full on November 25, 2013 by using proceeds from the first tranche of \$5 million the Company withdrew under the Hercules Credit Agreement entered into on November 25, 2013. Investment income was not significant in 2013 and 2012.

Other (expense) income

Other (expense) income for 2013 and 2012 was not significant.

*Comparison of Fiscal Year Ended December 31, 2012 and Fiscal Year Ended December 31, 2011.*

Licensing Revenue

We had no licensing revenue for the year ended December 31, 2012. In the first quarter of 2011, we recognized \$2 million in licensing revenue after amending our development, product supply and commercialization agreement for ThermoDox® with Yakult Honsha Co. to provide for accelerated payments of up to \$4 million in future milestone payments, including \$2 million that was paid to us on January 12, 2011, in exchange for a reduction in product approval milestones that we may receive in the future under the Yakult Agreement.

Research and Development Expenses

Research and Development (R&D) expenses decreased to \$15.8 million in 2012 compared to \$19.9 million in 2011. Costs associated with our Phase III HEAT study decreased to \$7.7 million in 2012 compared to \$12.1 million in 2011. This decrease is primarily the result of reaching enrollment targets for this pivotal study in the second quarter of 2012. Costs associated with our recurrent chest wall breast cancer clinical trial (RCW) remained relatively unchanged at \$0.4 million in 2012 and 2011. Costs associated with the Company's CRLM trial were \$0.2 million in 2012 compared to \$0.3 million in 2011. Other clinical related expenses decreased slightly to \$1.5 million in 2012 compared to \$1.6 million in 2011. Preclinical costs increased slightly to \$0.9 million in 2012 compared to \$0.8 million in 2011. Costs associated with regulatory activities increased to \$1.1 million in 2012 compared to \$0.6 million in 2011 as the Company prepared for a potential submission of a New Drug Application (NDA) in the event of positive data from the HEAT Study. Costs associated with the production of ThermoDox® decreased to \$4.0 million in 2012 compared to \$4.3 million in 2011 primarily due to the timing of registration batches and ongoing development of manufacturing capabilities for ThermoDox®.



General and Administrative Expenses

General and administrative expenses increased to \$6.4 million in 2012 compared to \$5.2 million in 2011. This increase is largely the result of an increase in professional fees related to product market analysis, business development activities, and personnel costs in 2012 compared to 2011.

Change in common stock warrant liability

A common stock warrant liability was incurred as a result of warrants issued in a public offering in September 2009. This liability is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. During 2012 we recorded a non-cash charge of \$4.1 million based on the change in this fair value in 2012. During 2011 we recorded a non-cash benefit of \$0.1 million based on the change in this fair value during 2011.

Investment income and interest expense

Investment income was \$0.1 million in 2012 compared to \$0.2 million in 2011. Interest expense in 2012 was \$0.4 million mostly as a result of interest charges the Company incurred in connection with the Company's \$5.0 million Venture Debt Loan facility. In connection with the shares of preferred stock we issued in our January 2011 preferred stock offering, we incurred dividend charges of approximately \$0.5 million in 2011.

Other (expense) income

Other (expense) income for 2012 and 2011 was not significant.

**Financial Condition, Liquidity and Capital Resources**

Since inception, excluding the net aggregate payments received from Boston Scientific of \$43 million through the divestiture of our medical device business in 2007 (which we received in installments of \$13 million in 2007 and \$15 million in each of 2008 and 2009), we have incurred significant losses and negative cash flows from operations. We

have financed our operations primarily through the net proceeds we received in this divesture, subsequent sales of equity, credit facilities and amounts received under our product licensing agreement with Yakult and our technology agreement with Hisun. The process of developing and commercializing ThermoDox® requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenues, and we had an accumulated deficit of \$169 million at December 31, 2013.

At December 31, 2013 we had total current assets of \$43.8 million (including cash, cash equivalents and short term investments and related interest receivable on short term investments of \$43.1 million) and current liabilities of \$4.7 million, resulting in net working capital of \$39.1 million. At December 31, 2012, we had total current assets of \$23.6 million (including cash and short term investments and related accrued interest on the short term investments of \$23.1 million) and current liabilities of \$5.0 million, resulting in working capital of \$18.6 million.

Net cash used in operating activities for the 2013 was \$9.5 million. Our 2013 net loss included \$1.2 million in non-cash stock-based compensation expense and \$8.1 million in non-cash benefit based on the change in the common stock warrant liability.

Net cash provided by financing activities was \$29.4 million during 2013 which consisted primarily of approximately \$6.7 million of net proceeds from sale of 1,195,923 shares of the Company's common stock in connection with the ATM Agreement, approximately \$13.6 million of net proceeds from sale of approximately 15,000 shares of the Company's Series A 0% convertible preferred stock and the warrants to purchase shares of its common stock in the Preferred Stock Offering, approximately \$8.9 million of net proceeds from the sale of 1,392,109 shares of its common stock and approximately \$0.4 million of gross proceeds from the exercise of options and warrants to purchase approximately 28,000 shares of the Company's common stock, each as adjusted to reflect the 4.5-to-1 reverse stock split made effective in October 2013

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5.0 million to support our development of ThermoDox® in the China territory.

The \$9.5 million net cash used in operating activities was mostly funded from cash and short term investments. At December 31, 2013, we had cash, cash equivalents and short term investments and related interest receivable on short term investments of \$43.1 million.

On November 25, 2013, the Company entered into the Hercules Credit Agreement, pursuant to which the Company may borrow a secured term loan of up to \$20 million in multiple tranches. The Company drew the first tranche of \$5 million at the closing on November 25, 2013 and used approximately \$4 million of the proceeds to repay the outstanding obligations under a loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation. The Company may request an additional \$15 million in up to three advances with each advance in a minimum amount of \$5 million, unless otherwise agreed upon by the Company and Hercules, before June 30, 2014 unless extended upon Hercules' consent. The loan bears an interest at a floating per annum rate equal to the greater of (i) 11.25 percent and (ii) the sum of 11.25 per cent plus the prime rate minus 3.25 per cent. Payments under the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

In January 2014, the Company sold in a registered direct offering, an aggregate of 3,603,604 shares of common stock and warrants to purchase up to 1,801,802 shares of Common Stock, for an aggregate purchase price of approximately \$15 million. The net proceeds from this offering to the Company were approximately \$13.8 million.

We believe that our cash and investment resources of \$43.1 million on hand at December 31, 2013, as well as the \$13.8 million of net proceeds the Company collectively received in the first quarter of 2014 from the January 2014 registered direct offering are sufficient to fund operations through 2016. However, our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash.

We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, or some combination of these financing alternatives. If we raise additional funds through the issuance of equity securities, the percentage ownership of our stockholders could be significantly diluted and the newly issued equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities may have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or

products on terms that are not favorable to us. The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. We also will continue to look for government sponsored research collaborations and grants to help offset future anticipated losses from operations and, to a lesser extent, interest income.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay or, reduce the scope of, or terminate our research, development, clinical programs, manufacturing, or commercialization efforts, or effect additional changes to our facilities or personnel, or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates, or products on terms not favorable to us.

### **Contractual Obligations**

In July 2011, the Company executed a lease (the Lease) with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The Lease has a term of 66 months and provides for 6 months rent free, with the first monthly rent payment of approximately \$23,000 due and paid in April 2012. Also, as required by the Lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the Lease Term has expired. In connection with the \$50,000 reduction of the standby letter of credit in April 2013, the Company reduced the escrow deposit by \$50,000.

Following is a summary of the future minimum payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2013:

For the year ending December 31:	<b>Capital</b>	<b>Operating</b>
	<b>Leases</b>	<b>Leases</b>
2014	\$ 11,303	\$ 286,243
2015	—	291,678
2016	—	297,113
2017	—	99,642
2018 and beyond	—	—
Total minimum lease payments	11,303	\$ 974,676
Less amounts of lease payments that represent interest	412	
Present value of future minimum capital lease payments	10,851	
Less current obligations under capital leases	10,851	
	\$—	

Following is a schedule of future principle payments under the Hercules Credit Agreement:

	<b>Hercules</b>
	<b>Credit</b>
	<b>Agreement</b>
For the year ending December 31:	
2014	\$
2015	1,827,115
2016	2,045,798
2017	1,127,087
	\$5,000,000

#### **Off-Balance Sheet Arrangements**

We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at December 31, 2013 by an immaterial amount. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instruments. As of December 31, 2013, our investments consisted of investments in corporate notes and obligations or in money market accounts and checking funds with variable market rates of interest. We believe our credit risk is immaterial.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements, supplementary data and report of independent registered public accounting firm are filed as part of this report on pages F-1 through F-32 and incorporated herein by reference.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

(a) Disclosure Controls and Procedures

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) under the supervision, and with the participation, of our management, including our principal executive officer and principal financial officer. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2013, which is the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is a process designed by, or under the supervision of, our chief executive officer and chief financial officer, or persons performing similar functions, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America (GAAP). Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary

to permit preparation of financial statements in accordance with GAAP and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework of 1992 (COSO Framework). Based on its evaluation, management has concluded that the Company's internal control over financial reporting is effective as of December 31, 2013.

This Annual Report on Form 10-K includes an attestation report of the Company's independent registered public accounting firm, Stegman and Company, regarding internal control over financial reporting.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. A control system, no matter how well designed and operated can provide only reasonable, but not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their cost.

(c) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting in the fiscal quarter ended December 31, 2013, which were identified in connection with our management's evaluation required by paragraph (d) of rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



(d) Inherent Limitations on the Effectiveness of Controls

Our management, including the chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures and our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

This Annual Report on Form 10-K includes an attestation report of the Company's independent registered public accounting firm, Stegman and Company, regarding internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item 10 is herein incorporated by reference to the definitive Proxy Statement to be filed with the Securities and Exchange Commission (SEC) pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 is herein incorporated by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item 12 is herein incorporated by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item 13 is herein incorporated by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item 14 is herein incorporated by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

## **PART IV**

### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

#### **1. FINANCIAL STATEMENTS**

The following is a list of the financial statements of Celsion Corporation filed with this Annual Report on Form 10-K, together with the reports of our independent registered public accountants and Management's Report on Internal Control over Financial Reporting.

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#### **2. FINANCIAL STATEMENT SCHEDULES**

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

#### **3. EXHIBITS**

The following documents are included as exhibits to this report:

**EXHIBIT NO. DESCRIPTION**

- 3.1 Certificate of Incorporation of Celsion, as amended, incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
- 3.2 Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to "Celsion Corporation" from "Celsion (Delaware) Corporation), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
- 3.3 Certificate of Amendment of the Certificate of Incorporation effective and filed on February 27, 2006, incorporated therein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed on March 1, 2006.
- 3.4 Certificate of Amendment to Certificate of Incorporation of Celsion Corporation, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on October 29, 2013.
- 3.5 By-laws of the Company, as amended and restated, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on December 1, 2011.
- 4.1 Form of Common Stock Certificate, par value \$0.01, incorporated herein by reference to Exhibit 4.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
- 4.2 Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on September 28, 2009.

- 4.3 Registration Rights Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd., incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on June 18, 2010.
- 4.4 Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on January 18, 2011.
- 4.5 Form of Common Stock Warrant incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on June 2, 2011.
- 4.6 Registration Rights Agreement, dated May 26, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company filed on June 2, 2011.
- 4.7 Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 6, 2011.
- 4.8 Registration Rights Agreement, dated July 25, 2011, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company filed on July 25, 2011.
- 4.9 Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 25, 2011.
- 4.10 Form of Warrant to Purchase Common Stock, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on July 25, 2011.
- 4.11 Form Warrant to Purchase Common Stock Purchase, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on December 6, 2011.
- 4.12 Registration Rights Agreement, dated December 1, 2011, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company filed on December 6, 2011.
- 4.13 Warrant to Purchase Stock, dated June 27, 2012, by and between Celsion Corporation and Oxford Financing LLC, incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 4.14 Warrant to Purchase Stock, dated June 27, 2012, by and between Celsion Corporation and Horizon Technology Finance Corporation, incorporated herein by reference to Exhibit 4.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 4.15 Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on February 26, 2013.
- 4.16 Form of Series A Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on January 21, 2014.

4.17 Form of Series B Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on January 21, 2014.

4.18 Warrant Agreement to Purchase Shares of the Common Stock dated as of November 25, 2013, by and between Celsion Corporation and Hercules Technology Growth Capital, Inc., incorporated herein by reference to Exhibit 4.2 to the Registration Statement on Form S-3 (File No.: 333-193936) filed on February 13, 2014.

Registration Agreement dated as of November 25, 2013, by and between Celsion Corporation and Hercules 4.19 Technology Growth Capital, Inc., incorporated herein by reference to Exhibit 4.3 to the Registration Statement on Form S-3 (File No.: 333-193936) filed on February 13, 2014.

- 10.1\*\*\* Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
- 10.2\*\*\* Celsion Corporation 2007 Stock Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 7, 2012.
- 10.3\*\*\* Form of Restricted Stock Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
- 10.4\*\*\* Form of Stock Option Grant Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
- 10.5\*\*\* Form of Restricted Stock Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.5 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
- 10.6\*\*\* Form of Stock Option Grant Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.6 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
- 10.7\*\*\* Stock Option Agreement effective January 3, 2007, between Celsion Corporation and Michael H. Tardugno, incorporated herein by reference Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on January 3, 2007.
- 10.8\*\*\* Employment Agreement, effective January 3, 2007, between Celsion Corporation and Mr. Michael H. Tardugno, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company filed on December 21, 2006.
- 10.9\*\*\* Employment Agreement, effective March 1, 2009, between the Company and Michael H. Tardugno, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on February 19, 2008.
- 10.10\*\*\* Employment Offer Letter, entered into on June 15, 2010, between the Company and Jeffrey W. Church, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 18, 2010.
- 10.11\* Patent License Agreement between the Company and Duke University dated November 10, 1999, incorporated herein by reference to Exhibit 10.9 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1999.
- 10.12\*



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License Agreement dated July 18, 2003, between the Company and Duke University, incorporated herein by reference to Exhibit 10.1 to the Registration Statement of the Company (File No. 333-108318) filed on August 28, 2003.

10.13\* Settlement and License Agreement dated February 7, 2007, by and among Celsion Corporation, American Medical Systems and AMS Research Corporation, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2007.

10.14\* Development, Product Supply and Commercialization Agreement, effective December 5, 2008, by and between the Company and Yakult Honsha Co., Ltd., herein by reference to Exhibit 10.15 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2008.

- 10.15\* The 2nd Amendment To The Development, Product Supply And Commercialization Agreement, effective January 7, 2011, by and between the Company and Yakult Honsha Co., Ltd. incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on January 18, 2011.
- 10.16 Lease Agreement, executed July 21, 2011, by and between Celsion Corporation and Brandywine Operating Partnership, L.P., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on July 25, 2011.
- 10.17\*\*\* Offer letter, dated July 8, 2011, by and between Celsion Corporation and Gregory Weaver, incorporated herein by reference to Exhibit 10.37 to the Annual Report on form 10-K/A of the Company for the year ended December 31, 2011.
- 10.18\*\*\* Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Michael H. Tardugno, incorporated herein by reference to Exhibit 10.38 to the Annual Report on Form 10-K/A of the Company for the year ended December 31, 2011.
- 10.19\*\*\* Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Gregory Weaver, incorporated herein by reference to Exhibit 10.39 to the Annual Report on Form 10-K/A of the Company for the year ended December 31, 2011.
- 10.20\*\*\* Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Nicholas Borys, M.D., incorporated herein by reference to Exhibit 10.40 to the Annual Report on Form 10-K/A of the Company for the year ended December 31, 2011.
- 10.21\*\*\* Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Jeffrey W. Church, incorporated herein by reference to Exhibit 10.41 to the Annual Report on Form 10-K/A of the Company for the year ended December 31, 2011.
- 10.22\*\*\* Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Robert A. Reed, incorporated herein by reference to Exhibit 10.42 to the Annual Report on Form 10-K/A of the Company for the year ended December 31, 2011.
- 10.23\* Technology Development Agreement effective as of May 7, 2012, by and between Celsion Corporation and Zhejiang Hisun Pharmaceutical Co. Ltd., incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 10.24 Loan and Security Agreement, dated June 27, 2012, by and among Celsion Corporation, Oxford Finance LLC, as collateral agent, and the lenders named therein, incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 10.25 Controlled Equity Offering<sup>SM</sup> Sales Agreement, dated February 1, 2013, by and between Celsion Corporation and Cantor Fitzgerald & Co., incorporated herein by reference to the Current Report on Form 8-K of the Company filed on February 1, 2013.
- 10.26 Securities Purchase Agreement, dated February 22, 2013, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on February 26, 2013.

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- 10.27\* Technology Development Contract dated as of January 18, 2013, by and between Celsion Corporation and Zhejiang Hisun Pharmaceutical Co. Ltd., incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2013.
- 10.28+ Loan and Security Agreement dated as of November 25, 2013, by and between Celsion Corporation and Hercules Technology Growth Capital, Inc.

10.29 Securities Purchase Agreement dated as of January 15, 2014, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on January 21, 2014.

23.1+ Consent of Stegman & Company, independent registered public accounting firm for the Company.

31.1+ Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2+ Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1^ Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2^ Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101\*\* The following materials from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the audited Balance Sheets, (ii) the audited Statements of Operations, (iii) the audited Statements of Cash Flows, and (iv) Notes to Financial Statements.

\* Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, amended, and the omitted material has been separately filed with the Securities and Exchange Commission.

+ Filed herewith.

^ Furnished herewith.

\*\* XBRL information is filed herewith.

\*\*\* Management contract or compensatory plan or arrangement.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused its annual report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

CELSION CORPORATION  
Registrant

March 13, 2014 By: */s/ MICHAEL H. TARDUGNO*  
Michael H. Tardugno  
President and Chief Executive Officer

March 13, 2014 By: */s/ JEFFREY W. CHURCH*  
Jeffrey W. Church  
Senior Vice President and Chief Financial Officer

Pursuant to the requirement of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

<b>Name</b>	<b>Position</b>	<b>Date</b>
<i>/s/ MICHAEL H. TARDUGNO</i> (Michael H. Tardugno)	President and Chief Executive Officer (Principal Executive Officer) and Director	March 13, 2014
<i>/s/ JEFFREY W. CHURCH</i> (Jeffrey W. Church)	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	March 13, 2014
<i>/s/ TIMOTHY J. TUMMINELLO</i> (Timothy J. Tumminello)	Controller and Chief Accounting Officer	March 13, 2014
<i>/s/ MAX E. LINK</i> (Max E. Link, PhD.)	Chairman of the Board, Director	March 13, 2014
<i>/s/ AUGUSTINE CHOW</i>	Director	March 13, 2014

(Augustine Chow, PhD.)

/s/ *FREDERICK J. FRITZ*  
(Frederick J. Fritz)

Director

March 13, 2014

/s/ *ROBERT W. HOOPER*  
(Robert W. Hooper)

Director

March 13, 2014

/s/ *ALBERTO MARTINEZ*  
(Alberto Martinez, MD)

Director

March 13, 2014

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Celsion Corporation

Lawrenceville, New Jersey

We have audited the accompanying balance sheets of Celsion Corporation (the “Company”) as of December 31, 2013 and 2012, and the related statements of operations, statements of comprehensive loss, changes in stockholders’ equity, and cash flows for each of the years in the three year period ended December 31, 2013. We also have audited the Company’s internal control over financial reporting as of December 31, 2013, based on criteria established in 1992 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company’s management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company’s internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have

a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Celsion Corporation as of December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Celsion Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in 1992 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

*/s/ Stegman & Company*  
Baltimore, Maryland  
March 13, 2014

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**CELSION CORPORATION****BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$5,718,504	\$14,991,488
Investment securities – available for sale	37,156,381	8,037,620
Accrued interest receivable on investment securities	212,048	65,925
Deposits on investigator grants	111,635	246,352
Vendor reimbursements receivable	161,764	116,872
Other current assets	401,787	190,727
	43,762,119	23,648,984
<b>Property and equipment</b> (at cost, less accumulated depreciation of \$1,264,190 and \$924,961, respectively),	832,886	1,114,621
<b>Other assets:</b>		
Deferred financing fees	844,249	306,495
Security deposit on letter of credit	200,000	250,000
Other assets	31,318	38,818
	1,075,567	595,313
<b>Total assets</b>	<b>\$45,670,572</b>	<b>\$25,358,918</b>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable – trade	\$1,452,436	\$2,339,768
Other accrued liabilities	2,707,653	1,254,979
Notes payable - current portion	10,891	1,410,455
Deferred revenue – current portion	500,000	
<b>Total current liabilities</b>	<b>4,670,980</b>	<b>5,005,202</b>
Common stock warrant liability	3,026	4,283,932
Note payable – non-current portion	5,000,000	3,661,147
Deferred revenue – non-current portion	4,000,000	
Other liabilities – noncurrent	472,731	446,779
<b>Total liabilities</b>	<b>14,146,737</b>	<b>13,397,060</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock - \$0.01 par value (75,000,000 shares authorized; 13,737,970 and 8,437,267 shares issued at December 31, 2013 and 2012 and 13,604,975 and 8,289,507 shares outstanding at December 31, 2013 and 2012, respectively)	137,380	84,373
	–	–

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Preferred Stock - \$0.01 par value (100,000 shares authorized, 20,000 and 5,000 shares issued and zero shares outstanding at December 31, 2013 and 2012, respectively)

Additional paid-in capital	203,139,142	170,957,891
Accumulated other comprehensive loss	(44,166 )	(126,607 )
Accumulated deficit	(169,287,157)	(156,263,288)
	33,945,199	14,652,369
Treasury stock, at cost (132,995 and 147,760 shares at December 31, 2013 and 2012, respectively)	(2,421,364 )	(2,690,511 )
<b>Total stockholders' equity</b>	31,523,835	11,961,858
<b>Total liabilities and stockholders' equity</b>	\$45,670,572	\$25,358,918

See accompanying notes to the financial statements.

**CELSION CORPORATION****STATEMENTS OF OPERATIONS**

	<b>Year ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Licensing revenue</b>	\$500,000	–	\$2,000,000
<b>Operating expenses:</b>			
Research and development	9,364,228	15,770,166	19,863,836
General and administrative	6,547,257	6,372,551	5,154,933
Total operating expenses	15,911,485	22,142,717	25,018,769
<b>Loss from operations</b>	(15,411,485)	(22,142,717)	(23,018,769)
<b>Other income (expense):</b>			
Gain (loss) from valuation of common stock warrant liability	8,090,636	(4,117,534 )	81,733
Investment (loss) income, net	(12,744 )	52,322	174,064
Interest expense	(915,235 )	(359,413 )	(501,855 )
Other (expense) income	(2,530 )	(1,040 )	42,149
Total other income (expense)	7,160,127	(4,425,665 )	(203,909 )
<b>Net loss</b>	(8,251,358 )	(26,568,382)	(23,222,678)
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	(4,601,410 )		
<b>Net loss attributable to common shareholders</b>	\$(12,852,768)	\$(26,568,382)	\$(23,222,678)
<b>Net loss per common share – basic and diluted</b>	\$(0.95 )	\$(3.44 )	\$(5.00 )
<b>Weighted average common shares outstanding – basic and diluted</b>	13,540,566	7,730,904	4,648,373

See accompanying notes to the financial statements.

**CELSION CORPORATION****STATEMENTS OF COMPREHENSIVE LOSS**

	<b>Year ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Net loss</b>	\$ (8,251,358)	\$ (26,568,382)	\$ (23,222,678)
Changes in:			
Realized loss on investment securities recognized in investment income, net	92,364	7,580	
Unrealized (loss) gain on investment securities	(9,923 )	142,513	(258,333 )
Other comprehensive income (loss)	82,441	150,093	(258,333 )
<b>Comprehensive loss</b>	\$ (8,168,917)	\$ (26,418,289)	\$ (23,481,011)

See accompanying notes to the financial statements

**CELSION CORPORATION**

**STATEMENTS OF CASH FLOWS**

	<b>Year ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$(8,251,358 )	\$(26,568,382)	\$(23,222,678)
Non-cash items included in net loss:			
Depreciation and amortization	339,229	281,489	169,358
Change in fair value of common stock warrant liability	(8,090,636 )	4,117,534	(81,733 )
Cash received for non-refundable research and development fee	5,000,000		
Deferred revenue	(500,000 )		
Stock based compensation - options	1,215,971	1,084,326	1,036,337
Stock based compensation – restricted stock	19,466	59,438	171,549
Shares issued out of treasury	62,546	57,239	60,360
Amortization of patent license fee	7,500	7,500	7,500
Shares issued in exchange for services	35,500	49,810	71,550
Deferred finance charges	336,387	43,215	
Change in deferred rent liability	(18,940 )	55,256	65,467
Net changes in:			
Prepaid expenses and other	(121,235 )	585,595	(393,676 )
Deposits and other assets	(116,181 )	18,721	4,167
Accounts payable	(887,332 )	(1,344,379 )	(538,383 )
Other accrued liabilities	1,497,566	(776,955 )	(92,255 )
<b>Net cash used in operating activities</b>	<b>(9,471,517 )</b>	<b>(22,329,593)</b>	<b>(22,742,437)</b>
<b>Cash flows from investing activities:</b>			
Purchases of investment securities	(66,376,818)	(16,208,958)	(10,659,238)
Proceeds from sale and maturity of investment securities	37,194,375	18,478,591	395,556
Refund (deposit) on security for letter of credit	50,000	–	(250,000 )
Purchases of property and equipment	(57,494 )	(613,390 )	(573,406 )
<b>Net cash (used in) provided by investing activities</b>	<b>(29,189,937)</b>	<b>1,656,243</b>	<b>(11,087,088)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from sale of preferred stock, net of issuance costs	13,616,432	–	4,324,080
Proceeds from sale of common stock equity, net of issuance costs	15,622,955	–	48,082,025
Proceeds from exercise of common stock warrants	261,944	10,106,557	428,337
Proceeds from exercise of common stock options	184,047	697,220	–
Proceeds from note payable	4,763,803	4,825,494	144,448
Principal payments on note payable	(5,060,711 )	(110,287 )	(142,427 )
<b>Net cash provided by financing activities</b>	<b>29,388,470</b>	<b>15,518,984</b>	<b>52,836,463</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(9,272,984 )</b>	<b>(5,154,366 )</b>	<b>19,006,938</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>14,991,488</b>	<b>20,145,854</b>	<b>1,138,916</b>

<b>Cash and cash equivalents at end of period</b>	\$5,718,504	\$14,991,488	\$20,145,854
<b>Cash paid for:</b>			
Interest	\$637,183	\$359,413	\$501,855
Income taxes	\$-	\$-	\$-

See accompanying notes to the financial statements

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## CELSION CORPORATION

## STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

## YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	Common Stock			Treasury Stock		Accum.	Accumulated Deficit	Total
	Outstanding	Additional		Shares	Amount	Other		
	Shares	Amount	Paid in Capital	Shares	Amount	Compr. Income		
<b>Balance at December 31, 2010</b>	2,962,465	\$31,314	\$99,426,459	168,949	\$(3,076,670)	\$(18,367 )	\$(100,938,261 )	\$(4,575,525 )
Net loss	-	-	-	-	-	-	(23,222,678 )	(23,222,678 )
Unrealized loss on investments available for sale	-	-	-	-	-	(258,333)	-	(258,333 )
Valuation of common stock warrants in connection with issuance of 8% Series A Redeemable, Convertible Preferred Stock	-	-	2,030,000	-	-	-	-	2,030,000
Conversion of 8% Series A Redeemable, Convertible Preferred Stock	462,960	4,630	2,626,717	-	-	-	-	2,631,347
Valuation of beneficial conversion feature associated	-	-	5,386,518	-	-	-	(5,386,518 )	-

with the 8% Series A Redeemable, Convertible Preferred Stock									
Shares issued under CEFF, net of issuance costs	297,892	2,979	3,113,108	-	-	-	-	-	3,116,087
Registered Direct and Private Placement	3,584,306	35,843	44,668,694	-	-	-	-	-	44,704,537
Placement common stock offerings									
Conversion of common stock warrants	34,859	348	427,988	-	-	-	-	-	428,337
Stock-based compensation expense	-	-	1,207,886	-	-	-	-	-	1,207,886
Issuance of restricted stock upon vesting	21,692	217	(217 )	-	-	-	-	-	-
Issuance of common stock out of treasury	10,565	-	249	(10,565 )	192,545	-	(60,884 )		131,910
<b>Balance at December 31, 2011</b>	<b>7,374,739</b>	<b>\$75,332</b>	<b>\$158,887,402</b>	<b>158,384</b>	<b>\$(2,884,125)</b>	<b>\$(276,700)</b>	<b>\$(129,608,341)</b>		<b>\$26,193,568</b>



## CELSION CORPORATION

## STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (continued)

## YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	Common Stock			Treasury Stock		Accum.	Accumulated Deficit	Total
	Outstanding	Additional		Shares	Amount	Other		
	Shares	Amount	Paid in Capital	Shares	Amount	Compr. Income		
<b>Balance at December 31, 2011</b>	7,374,739	\$75,332	\$158,887,403	158,384	\$(2,884,125)	\$(267,700)	\$(129,608,341)	\$26,193,568
Net loss	-	-	-	-	-	-	(26,568,382 )	(26,568,382)
Unrealized gain on investments available for sale	-	-	-	-	-	150,093	-	150,093
Valuation of common stock warrants in connection with notes payable	-	-	73,654	-	-	-	-	73,654
Conversion of common stock warrants	845,526	8,455	10,156,437	-	-	-	-	10,164,892
Stock-based compensation expense	-	-	1,143,764	-	-	-	-	1,143,764
Issuance of restricted stock and option exercise	58,618	586	696,643	-	-	-	-	697,220
Issuance of common stock out of treasury	10,624	-	-	(10,624 )	193,614	-	(86,565 )	107,049
	8,289,507	\$84,373	\$170,957,891	147,760	\$(2,690,511)	\$(126,607)	\$(156,263,288)	\$11,961,858

**Balance at  
December 31,  
2012**

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## CELSION CORPORATION

## STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (continued)

## YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	Preferred Stock		Common Stock		Additional Paid in Capital	Treasury Stock		Accum. Other Compr. Income	Accumulated Deficit
	Outstanding Shares	Amount	Outstanding Shares	Amount		Shares	Amount		
<b>Balance at December 31, 2012</b>			8,289,507	\$84,373	\$170,957,891	147,760	\$(2,690,511)	\$(126,607)	\$(156,263,2
Net loss	-	-	-	-	-	-	-	-	(8,251,358
Preferred stock offering	15,001	150	-	-	18,217,702	-	-	-	-
Non-cash dividend on beneficial conversion feature associated with the preferred stock offering	-	-	-	-	-	-	-	-	(4,601,410
Conversion of preferred stock	(15,001)	(150)	2,682,759	26,828	(26,678 )	-	-	-	-
Registered Direct and ATM common stock offerings	-	-	2,588,032	25,880	15,598,670	-	-	-	-
Classification of warrants to/from common stock warrant liability, net	-	-	-	-	(3,809,730 )	-	-	-	-
Conversion of common stock warrants	-	-	18,021	180	261,764	-	-	-	-
	-	-	-	-	521,763	-	-	-	-

Valuation of common stock warrants in connection with notes payable									
Unrealized gain on investments available for sale	-	-	-	-	-	-	-	82,441	-
Stock-based compensation expense	-	-	-	-	1,235,437	-	-	-	-
Issuance of restricted stock and option exercise	-	-	12,872	129	183,918	-	-	-	-
Issuance of common stock out of treasury	-	-	14,765	-	-	(14,765)	269,147	-	(171,101)
Fractional share payment	-	-	(981)	(10)	(1,595)	-	-	-	-
<b>Balance at December 31, 2013</b>	-	\$-	13,604,975	\$137,380	\$203,139,142	132,995	\$(2,421,364)	\$(44,166)	\$(169,287,101)

See accompanying notes to the financial statements

CELSION CORPORATION

**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011**

## **1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### *Description of Business*

Celsion Corporation, referred to herein as “Celsion”, “We”, or “the Company,” a Delaware corporation based in Lawrenceville, New Jersey, is an oncology drug development company focused on improving treatment for those suffering with difficult to treat forms of cancer. We are working to develop and commercialize more efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. Our lead product ThermoDox® is being tested in human clinical trials for the treatment of primary liver cancer and recurrent chest wall breast cancer.

### *Basis of Presentation*

The accompanying financial statements of Celsion have been prepared in accordance with generally accepted accounting principles (“GAAP”) in the United States and include the accounts of the Company. The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates, and assumptions that affect the amount reported in the Company’s financial statements and accompanying notes. Actual results could differ materially from these estimates.

Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements and accompanying notes. No events and conditions would give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business. See Note 16 for a summary of subsequent events.

Certain items in the prior period financial statements have been reclassified to conform to the current period presentation.

*Revenue Recognition*

At the inception of each collaborative agreement that includes milestone payments, the Company evaluates whether each milestone is substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required. Milestones that are not considered substantive and that do not meet the separation criteria are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance. Payments received or reasonably assured after performance obligations are met completely are recognized as earned.

*Cash and Cash Equivalents*

Cash and cash equivalents include cash on hand and investments purchased with an original maturity of three months or less. A portion of these funds are not covered by FDIC insurance.

*Fair Value of Financial Instruments*

The carrying values of financial instruments approximate their respective fair values.

*Short Term Investments*

The Company classifies its investments in marketable securities with readily determinable fair values as investments available-for-sale in accordance with Accounting Standards Codification (ASC) 320, *Investments - Debt and Equity Securities*. Available-for-sale securities consist of debt and equity securities not classified as trading securities or as securities to be held to maturity. The Company has classified all of its investments as available-for-sale. Unrealized holding gains and losses on available-for-sale securities are reported as a net amount in accumulated other comprehensive gain or loss in stockholders' equity until realized. Gains and losses on the sale of available-for-sale securities are determined using the specific identification method. The Company's short term investments consist of corporate bonds and government agency bonds.

### *Property and Equipment*

Property and equipment is stated at cost less accumulated depreciation. Depreciation is provided over the estimated useful lives of the related assets, ranging from three to seven years, using the straight-line method. Major renewals and improvements are capitalized at cost and ordinary repairs and maintenance are charged against operating expenses as incurred. Depreciation expense was approximately \$339,000, \$281,500 and \$169,000 for years ended December 31, 2013, 2012 and 2011, respectively.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered impaired if its carrying amount exceeds the future net undiscounted cash flows that the asset is expected to generate. If such asset is considered to be impaired, the impairment recognized is the amount by which the carrying amount of the asset, if any, exceeds its fair value determined using a discounted cash flow model.

### *Deposits*

Deposits include real property security deposits and other deposits which are contractually required and of a long-term nature.

### *Patent Licenses*

The Company has purchased several licenses for rights to patented technologies. Patent license costs of \$63,125 have been capitalized and are amortized on a straight-line basis over the estimated life of the related patent. As of December 31, 2013, the total accumulated amortization expense is \$34,000. The weighted-average amortization period for these assets is 10 years.

### *Comprehensive Income (Loss)*

ASC 220, *Comprehensive Income*, establishes standards for the reporting and display of comprehensive income and its components in the Company's consolidated financial statements. The objective of ASC 220 is to report a measure (comprehensive income (loss)) of all changes in equity of an enterprise that result from transactions and other economic events in a period other than transactions with owners.

*Research and Development*

Research and development costs are expensed as incurred. Equipment and facilities acquired for research and development activities that have alternative future uses are capitalized and charged to expense over their estimated useful lives.

*Net Loss Per Common Share*

Basic and diluted net income/(loss) per common share was computed by dividing net income/(loss) for the year by the weighted average number of shares of Common Stock outstanding, both basic and diluted, during each period. The impact of Common Stock equivalents has been excluded from the computation of diluted weighted average common shares outstanding in periods where there is a net loss, as their effect is anti-dilutive.

For the years ended December 31, 2013, 2012 and 2011, outstanding equity awards of 863,462, 729,825 and 704,113 shares, respectively, and warrants outstanding to purchase 3,268,013, 1,749,667 and 2,577,470 shares, respectively, were considered anti-dilutive and therefore were not included in the calculation of diluted shares.



### *Income Taxes*

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax asset and liabilities of a change in tax rates is recognized in results of operations in the period that the tax rate change occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In accordance with ASC 740, *Income Taxes*, a tax position is recognized as a benefit only if it is “more likely than not” that the tax position taken would be sustained in a tax examination, presuming that a tax examination will occur. The Company recognizes interest and/or penalties related to income tax matters in the income tax expense category. The Company remains subject to examination for income tax returns for the years ending after 2010.

### *Stock-Based Compensation*

Compensation costs for all stock-based awards is measured at fair value on the date of the grant and recognized over the service period for awards expected to vest. Such value is recognized as expense over the service period. The estimation of stock-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the current estimates, such amounts will be recorded as cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience.

### *Recent Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by FASB and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on the Company’s consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

## **2. FINANCIAL CONDITION**

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company’s research and development programs, clinical trials conducted in connection with the Company’s product

candidates, and applications and submissions to the Food and Drug Administration. The Company believes these expenditures are essential for the commercialization of its technologies. As a result of these expenditures, as well as general and administrative expenses, the Company has an accumulated deficit of \$169 million as of December 31, 2013.

The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes marketing and sales activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, produce, and market and sell its new product candidates. There can be no assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past. The Company expects that its operating results will fluctuate significantly in the future and will depend on a number of factors, many of which are outside the Company's control.

The Company will need substantial additional funding in order to complete the development, testing and commercialization of its oncology product candidates and we have made a significant commitment to heat-activated liposome research and development projects and it is our intention at least to maintain, and possibly increase, the pace and scope of these activities. The commitment to these new projects will require additional external funding, at least until the Company is able to generate sufficient cash flow from sale of one or more of its products to support its continued operations.

If adequate funding is not available, the Company may be required to delay, scale back or terminate certain aspects of its operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force it to relinquish rights to certain of its technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if the Company cannot fund its ongoing development and other operating requirements, particularly those associated with its obligations to conduct clinical trials under its licensing agreements, it will be in breach of these licensing agreements and could therefore lose its license rights, which could have material adverse effects on its business. Management is continuing its efforts to obtain additional funds so that the Company can meet its obligations and sustain operations.

### 3. SHORT TERM INVESTMENTS AVAILABLE FOR SALE

Short term investments available for sale of \$37,156,381 and \$8,037,620 as of December 31, 2013 and 2012, respectively, consist of money market funds, commercial paper, corporate debt securities, and government agency debt securities. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in Accumulated Other Comprehensive Income.

Securities available for sale are evaluated periodically to determine whether a decline in their value is other than temporary. The term "other than temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. Once a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized.

<b>Short-term investments available for sale, at fair value</b>	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
Bonds – corporate issuances	\$37,156,381	\$8,037,620

A summary of the cost, fair value and maturities of the Company's short-term investments is as follows:

	<b>December 31, 2013</b>		<b>December 31, 2012</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Short-term investments</b>				
Bonds- corporate issuances	\$37,200,576	\$37,156,381	\$8,164,227	\$8,037,620
<b>Bond maturities</b>				
Within 3 months	\$7,799,032	\$7,797,689	\$3,053,740	\$3,002,350
Between 3-12 months	29,401,543	29,358,692	5,110,487	5,035,270
<b>Total</b>	<b>\$37,200,576</b>	<b>\$37,156,381</b>	<b>\$8,164,227</b>	<b>\$8,037,620</b>

Investment income, which includes net realized losses on sales of available for sale securities and investment income interest and dividends, is summarized as follows:

<b>2013</b>	<b>2012</b>	<b>2011</b>
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Interest and dividends accrued and paid	\$748,947	\$712,947	\$32,289
Accretion of investment premium	(669,344)	(652,960)	
Losses on investment maturity and sales, net	(92,346 )	(7,580 )	
	\$(12,744 )	\$52,322	\$32,289

In 2009, the Company recorded an equity investment of approximately \$108,000 for stock received as settlement of a transition agreement the Company previously entered into. The \$108,000 asset value reflected the estimated net realizable value of 903,112 shares of Med focus Inc at the time of settlement. As of December 31, 2011, this entire amount had been reduced to \$0 and was charged as an unrealized loss in other comprehensive loss. During the 4th quarter of 2012, the Company sold this stock for approximately \$138,000, thereby recording a realized gain of approximately \$30,000 in investment income and reversing the cumulative unrealized loss of \$108,000 in other comprehensive loss.

The following table shows the Company's investment securities gross unrealized losses and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at December 31, 2012 and 2011. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

December 31, 2013	Less than 12 months	12 months or Longer		Total	Gross Unrealized Holding (Losses) Gains
		Gross Unrealized Holding Losses	Fair Value Holding Losses		
Available for Sale					
Bonds – corporate issuances	\$37,156,381	\$(44,195 )	–	–	\$37,156,381 \$(44,195 )

December 31, 2012	Less than 12 months	12 months or Longer		Total	Gross Unrealized Holding (Losses) Gains
		Gross Unrealized Holding Losses	Fair Value Holding Losses		
Available for Sale					
Bonds – corporate	\$8,037,620	\$(126,607 )	–	–	\$8,037,620 \$(126,607 )

#### 4. FAIR VALUES OF FINANCIAL INSTRUMENTS

FASB Accounting Standards Codification (ASC) Section 820, *Fair Value Measurements and Disclosures*, establishes a three tier level hierarchy for fair value measurements which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1: Quoted prices (unadjusted) or identical assets or liabilities in active markets that the entity has the ability to access as of the measurement date.

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3: Significant unobservable inputs that reflect a reporting entity's own assumptions that market participants would use in pricing an asset or liability.

The fair values of securities available for sale are determined by obtaining quoted prices on nationally recognized exchanges (Level 1 inputs) or matrix pricing, which is a mathematical technique widely used in the industry to value debt securities without relying exclusively on quoted prices for the specific securities but rather by relying on the securities' relationship to other benchmark quoted securities (Level 2 inputs).

Cash and cash equivalents, other current assets, accounts payable and other accrued liabilities are reflected in the balance sheet at their estimated fair values primarily due to their short-term nature. The common stock warrant liability has been valued using the Black-Scholes option pricing model, the inputs of which are more fully described in Note 11 to the financial statements. There were no transfers of assets or liabilities between Level 1 and Level 2 and no transfers in or out of Level 3 during 2013 except for the change in the fair market value of the warrant liability was included in earnings.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	<b>Total Fair Value on the Balance Sheet</b>	<b>Quoted Prices In Active Markets For Identical Assets /Liabilities (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>Assets:</b>				
As of December 31, 2013				
Short-term investments available for sale				
Bonds – corporate issuances	\$37,156,381	\$37,156,381	\$ –	\$ –
As of December 31, 2012				
Short-term investments available for sale				
Bonds – corporate issuances	\$8,037,620	\$8,037,620	\$ –	\$ –
<b>Liabilities:</b>				
As of December 31, 2013				
Common stock warrant liability	\$3,026	\$–	\$ –	\$ 3,026
As of December 31, 2012				
Common stock warrant liability	\$4,283,932	\$–	\$ –	\$ 4,283,932

## 5. PROPERTY, PLANT AND EQUIPMENT:

	<b>December 31, 2013</b>	<b>December 31, 2012</b>
Machinery and equipment (5-7 year life)	\$1,674,206	\$1,618,673
Furniture and fixtures (3-5 year life)	153,051	164,559
Leasehold improvements (5-7 year life)	269,819	256,350
	2,097,076	2,039,582
Less accumulated depreciation and amortization	(1,264,190)	(924,961 )

Total	\$832,886	\$1,114,621
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## 6. OTHER ACCRUED LIABILITIES

	<b>December 31,</b>	<b>December 31,</b>
	<b>2013</b>	<b>2012</b>
Other accrued liabilities at December 31, 2013 and 2012 include the following		
Amounts due to Contract Research Organizations and other contractual agreements	\$1,711,934	\$827,989
Accrued payroll and related benefits	900,434	338,365
Accrued professional fees	63,500	37,400
Other	31,785	51,225
Total	\$2,707,653	\$1,254,979

## 7. NOTES PAYABLE

### *Hercules Credit Agreement*

On November 25, 2013, the Company entered into a loan agreement with Hercules Technology Growth Capital, Inc. (“Hercules”) which permits up to \$20 million in capital to be distributed in multiple tranches (the “Hercules Credit Agreement”). The Company drew the first tranche of \$5 million upon closing of the Hercules Credit Agreement on November 25, 2013 and used approximately \$4 million of the proceeds to repay the outstanding obligations under its loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation as discussed further below. The Company anticipates that it will use any additional funding up to \$15 million as provided under the agreement for working capital or in support of its previously announced strategic acquisition initiative, which is designed to identify new technologies and clinical stage products for its development pipeline.



The obligations under the Hercules Credit Agreement are in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception). Payments under the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

As a fee in connection with the Hercules Credit Agreement, the Company issued Hercules a warrant exercisable for a total of 194,986 shares of Celsion's common stock (the "Hercules Warrant") at a per share exercise price of \$3.59, with 50% immediately exercisable for cash or by net exercise from November 25, 2013 and the remaining 50% to be exercisable upon Hercules funding any subsequent tranches. The Hercules Warrant will expire November 25, 2018. Hercules has certain rights to register the common stock underlying the Warrant pursuant to a Registration Rights Agreement with Celsion dated November 25, 2013. The registration rights expire on the date when such stock may be sold under Rule 144 without restriction or upon the first year anniversary of the registration statement for such stock, whichever is earlier.

The Company valued the Hercules Warrant using the Black-Scholes option pricing model and recorded \$521,763 as deferred financing fees. In calculating the value of the warrants, the Company assumed a volatility rate of 102%, risk free interest rate of 1.37%, an expected life of 5 years, a stock price of \$3.55 (closing price on date of the Hercules Warrant) and no expected forfeitures nor dividends. In connection with the Credit Agreement, the Company incurred cash expenses of \$352,378 which were recorded as deferred financing fees. These deferred financing fees are being amortized as interest expense using the effective interest method over the life of the loan. For the period since the Hercules Credit Agreement's inception through December 31, 2013, the Company incurred \$57,813 in interest expense and amortized \$29,892 in deferred financing fees as interest expense.

The Hercules Credit Agreement contains customary covenants, including covenants that limit or restrict Celsion's ability to grant liens, incur indebtedness, make certain restricted payments, merge or consolidate and make dispositions of assets. Upon the occurrence of an event of default under the Hercules Credit Agreement, the lenders may cease making loans, terminate the Hercules Credit Agreement, declare all amounts outstanding to be immediately due and payable and foreclose on or liquidate Celsion's assets that comprise the lenders' collateral. The Hercules Credit Agreement specifies a number of events of default (some of which are subject to applicable grace or cure periods), including, among other things, non-payment defaults, covenant defaults, a material adverse effect on Celsion or its assets, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults and material judgment defaults. The Company has maintained compliance with these covenants.

Following is a schedule of future principle payments due on the Hercules Credit Agreement:

**Hercules**

**Credit**

**Agreement**

For the year ending December 31:

2014	\$
2015	1,827,115
2016	2,045,798
2017	1,127,087
	\$5,000,000

***Oxford & Horizon Credit Agreement***

In June 2012, the Company entered into a Loan and Security Agreement (the “Oxford & Horizon Credit Agreement”) with Oxford Finance LLC (“Oxford”) and Horizon Technology Finance Corporation (“Horizon”). The Oxford & Horizon Credit Agreement provided for a secured term loan of up to \$10 million, with 50% of any loans to be funded by Oxford and 50% to be funded by Horizon. The aggregate loan amount could have been advanced in two tranches of \$5 million each. The first tranche (the “Term A Loan”) was made available to the Company on June 27, 2012 and the second tranche (the “Term B Loan”) was to be made available, if at all, during the period beginning on the date that the Company achieved positive data in its Phase III clinical trial of RFA and ThermoDox® (the HEAT Study) and ending on March 31, 2013. On January 31, 2013, the Company announced it did not meet the primary endpoint of the HEAT Study.

The Term A Loan was originally scheduled to mature on October 15, 2015. As a result of the Hercules Credit Agreement discussed above, the Company terminated the Oxford & Horizon Credit Agreement and repaid the outstanding principle, accrued interest and termination fees totaling approximately \$4.1 million.

The proceeds of the Oxford & Horizon Credit Agreement were used to fund the Company's working capital and general corporate purposes. The obligations under the Oxford & Horizon Credit Agreement were secured by substantially all assets of the Company other than its intellectual property and certain other agreed-upon exclusions.

The Company used approximately \$4 million of the proceeds from the Hercules Credit Agreement to repay the outstanding obligations under the Oxford & Horizon Credit Agreement in November 2013. During 2013 through the termination of the Oxford & Horizon Credit Agreement in November 2013, the Company paid \$572,264 in interest expense and amortized the remaining \$248,160 of deferred financing fees as interest expense. For the period from the Oxford & Horizon Credit Agreement's inception in June 2012 through December 31, 2012, the Company paid \$300,278 in interest expense and amortized \$43,215 in deferred financing fees as interest expense.

The Term A Loan bore interest at a fixed rate of 11.75%. However, for an initial period extending for the Term A Loan through May 1, 2013, the Company was only required to make interest payments. The Company was also obligated to pay other customary facility fees for a credit facility of this size and type.

The Oxford & Horizon Credit Agreement contained customary covenants, including covenants that limited or restricted the Company's ability to incur liens, incur indebtedness, make certain restricted payments, merge or consolidate or make dispositions of assets. Upon the occurrence of an event of default under the Credit Agreement, the lenders could have ceased making loans, terminated the Oxford & Horizon Credit Agreement, declared all amounts outstanding to be immediately due and payable and foreclosed on and/or liquidated the Company's assets that comprised the lenders' collateral. The Oxford & Horizon Credit Agreement specified a number of events of default (some of which are subject to applicable grace or cure periods), including, among other things, non-payment defaults, covenant defaults, a material adverse change in the Company's business, cross-defaults to other materials indebtedness, bankruptcy and insolvency defaults and material judgment defaults. The Company was in compliance with these covenants up to and through the time of its termination and payroll.

As a fee in connection with the Oxford & Horizon Credit Agreement, the Company issued warrants to Horizon and Oxford (the "Oxford & Horizon Warrants") to purchase the number of shares of the Company's common stock equal to 3% of each loan amount divided by the exercise price, which was calculated as the average NASDAQ closing price of The Company common stock for the three days prior to the funding of the loan amount (\$2.92 per share for the Term A Loan). This resulted in 11,415 warrant shares issued in connection with the Term A Loan. The Oxford & Horizon Warrants issued in connection with the Term A Loan are exercisable for cash or by net exercise and will expire seven years after their issuance, which is June 27, 2019.

The Company valued the Oxford & Horizon Warrants using the Black-Scholes option pricing model and recorded \$73,654 as deferred financing fees. In calculating the value of the warrants, the Company assumed a volatility rate of 74.3%, risk free interest rate of 1.10%, an expected life of 3.5 years, a stock price of \$2.80 (closing price on date of the Oxford & Horizon Warrant) and no expected forfeitures nor dividends. In connection with the Oxford & Horizon Credit Agreement, the Company incurred cash expenses of \$217,715 which were recorded as deferred financing fees in 2012. These deferred financing fees were amortized as interest expense over the life of the loan.

### ***Capital Equipment Lease***

In November 2011, the Company financed \$144,448 of lab equipment through a capital lease. This lease obligation has thirty monthly payments of \$5,651 through February 2014. During 2013, the Company made principal and interest payments totaling \$67,817. The outstanding lease obligation is \$10,891 as of December 31, 2013. See Note 15 to the financial statements.

**8. INCOME TAXES**

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2013, 2012 and 2011 is as follows:

	<b>2013</b>	<b>2012</b>	<b>2011</b>
Federal statutory rate	34.0 %	34.0 %	34.0 %
State taxes, net of federal tax benefit	5.9	5.9	4.6
Recapture of alternative minimum tax	-	-	-
Valuation allowance	(39.9)	(39.9)	(38.6)
Effective tax rate	- %	- %	- %

The components of the Company's deferred tax asset as of December 31, 2013 and 2012 are as follows:

<i>In thousands</i>	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
Net operating loss carry forwards	\$53,423	\$49,274
Compensation expense related to employee stock options	3,310	2,817
Subtotal	56,733	52,091
Valuation allowance	(56,733)	(52,091)
Total deferred tax asset	\$-	\$-

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors that affect the Company's ability to generate future taxable income, such as intent and ability to sell assets and historical and projected operating performance. At this time, the Company has established a valuation reserve for all of its deferred tax assets. Such tax assets are available to be recognized and benefit future periods.

Following is a schedule of net operating loss carry forwards and their year of expiration:

<b>Approximate Amount  Of Unused Operating</b>	<b>Expiration During Year  Ended</b>
----------------------------------------------------------------	------------------------------------------------------

**Loss Carry  
Forwards**

**(in \$000s)**

\$ 4,843	2022
2,293	2023
15,647	2024
8,168	2025
7,361	2026
11,905	2028
18,547	2029
18,145	2030
21,386	2031
20,558	2032
10,397	2033
\$ 139,250	

During 2013, 2012 and 2011 the Company performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit its ability to utilize certain net operating loss and tax credit carry forwards. The Company determined that it experienced an ownership change, as defined by Section 382, in connection with certain common stock offerings on July 25, 2011, February 5, 2013 and on June 3, 2013. As a result, the utilization of the Company's federal tax net operating loss carry forwards generated prior to the ownership changes are limited. As of December 31, 2013, the Company has net operating loss carry forwards for U.S. federal and state tax purposes of approximately \$139 million, before excluding net operating losses that have been limited as a result of Section 382 limitations. The annual limitation due to Section 382 for net operating loss carry forward utilization is approximately \$4.9 million per year for approximately \$90 million in net operating loss carry forwards existing at the ownership change occurring on July 25, 2011, approximately \$1.4 million per year for approximately \$34 million of additional net operating losses occurring from July 2011 to the ownership change that occurred on February 5, 2013 and approximately \$1.5 million per year for approximately \$34 million of additional net operating losses occurring from February 5, 2013 to the ownership change that occurred on June 3, 2013. The utilization of these net operating loss carry forwards may be further limited if the Company experiences future ownership changes as defined in Section 382 of the Internal Revenue Code.

## 9. STOCKHOLDERS' EQUITY

In August 2012, the Company filed with the Securities and Exchange Commission a \$75 million shelf registration statement on Form S-3 that allowed the Company to issue any combination of common stock, preferred stock or warrants to purchase common stock or preferred stock. This shelf registration was declared effective on September 14, 2012.

During 2013, we received approximately \$0.4 million of gross proceeds from the exercise of warrants and stock options to purchase approximately 30,451 shares of the Company's common stock. During 2012, we received approximately \$10.8 million of gross proceeds from the exercise of warrants and stock options to purchase approximately 904,144 shares of the Company's common stock. During 2011, we received approximately \$0.4 million of gross proceeds from the exercise of warrants and stock options to purchase approximately 34,859 shares of the Company's common stock.

### Controlled Equity Offering

On February 1, 2013, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "ATM Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which Celsion may offer and sell, from time to time, through Cantor, shares of our common stock having an aggregate offering price of up to \$25.0 million (the "ATM Shares") pursuant to the Company's previously filed and effective Registration Statement on Form S-3. Under the ATM Agreement, Cantor may sell ATM Shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for the our common stock or to or through a market maker. From February 1, 2013 through February 25, 2013, the Company sold and issued an aggregate of 1,195,927 shares of common stock under the ATM Agreement, receiving approximately \$6.8 million in net proceeds.

The Company is not obligated to sell any ATM Shares under the ATM Agreement. Subject to the terms and conditions of the ATM Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market, to sell ATM Shares from time to time based upon the Company's instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. In addition, pursuant to the terms and conditions of the ATM Agreement and subject to the instructions of the Company, Cantor may sell ATM Shares by any other method permitted by law, including in privately negotiated transactions.

The ATM Agreement will terminate upon the earlier of (i) the sale of ATM Shares under the ATM Agreement having an aggregate offering price of \$25 million and (ii) the termination of the ATM Agreement by Cantor or the Company.

The ATM Agreement may be terminated by Cantor or the Company at any time upon 10 days' notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company pays Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of ATM Shares and has agreed to provide Cantor with customary indemnification and contribution rights. The Company also reimbursed Cantor for legal fees and disbursements of \$50,000 in connection with entering into the ATM Agreement. In connection with the February 2013 Preferred Stock Offering discussed below, the Company agreed to not sell any ATM Shares for a period of one year from February 26, 2013. In connection with the Common Stock Offering below, the Company agreed to not sell any ATM Shares until June 3, 2014. In connection with the January 2014 securities offering discussed in Note 15 below, the Company agreed to not sell any ATM Shares until July 22, 2014. The Company currently has approximately \$18 million remaining under the ATM Agreement.



February 2013 Preferred Stock Offering

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 15,000.00422 shares of its Series A 0% convertible preferred stock and the warrants to purchase shares of its common stock, for an aggregate purchase price of approximately \$15.0 million (the February 2013 Preferred Stock Offering). The closing of the February 2013 Preferred Stock Offering occurred on February 26, 2013, in which the Company received approximately \$15.0 million in gross proceeds. Subject to certain ownership limitations, shares of Series A 0% convertible preferred stock are convertible, at the option of the holder thereof, into an aggregate of up to 2,682,764 shares of common stock, and the warrants are exercisable to purchase an aggregate of up to 1,341,382 shares of common stock. Each warrant has an exercise price of \$5.31 per share, equal to the closing bid price of common stock on February 21, 2013. The warrants are immediately exercisable and expire five years after the date of issuance.

Upon issuance, we estimated the fair value of the warrants issued in the February 2013 Preferred Stock Offering to be approximately \$5.4 million using the Black-Scholes pricing model. Also, upon issuance, we recognized approximately \$4.6 million as a one-time, non-cash deemed dividend related to the beneficial conversion feature connected to the preferred stock in the Preferred Stock Offering.

Assumptions used in the valuation of the warrants issued in the February 2013 Preferred Stock Offering are as follows:

Risk-free interest rate	0.78	%
Expected volatility	102.23	%
Expected life (in years)	5.0	
Expected forfeiture rate	0.0	%
Expected dividend yield	0.0	%

As of September 30, 2013, all 2,682,764 shares of common stock in the aggregate were issued upon conversion of all 15,000.00422 shares of the Series A 0% convertible preferred stock.

May 2013 Common Stock Offering

On May 30, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 1,392,109 shares of its common stock for an aggregate purchase price of approximately \$9.8 million (the “Common Stock Offering”). The closing of the

Common Stock Offering occurred on June 3, 2013. The issuance of common stock in the Common Stock Offering was made pursuant to the Company's previously filed and effective Registration Statement on Form S-3 (File No. 333-183286), the base prospectus dated September 14, 2012 filed as part of such Registration Statement, and the prospectus supplement filed with the Securities and Exchange Commission on June 3, 2013. The Securities Purchase Agreement also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

Prior to the closing of the Common Stock Offering, there were an insufficient number of authorized shares to complete the transaction. The investors in the Common Stock Offering also held warrants to purchase common stock of the Company which were issued in connection with previous offerings. Concurrent with the closing of the Common Stock Offering, the institutional investors agreed to waive their rights to exercise these warrants to purchase 1,398,816 shares of common stock of the Company (the "Waived Warrants") until the Company has obtained stockholders' approval to increase the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock. At the Company's 2013 Annual Meeting of Stockholders held on July 19, 2013, the Company's stockholders voted to approve the proposal to grant discretionary authority to the Board of Directors to amend the Certificate of Incorporation of the Company, as amended, to effect, at any time on or prior to the date of the 2014 Annual Meeting of Stockholders, a reverse stock split at an exchange ratio within the specified range and to set the number of authorized shares effective immediately after the reverse stock split at 75 million shares. On October 28, 2013, the Company announced that it effected a 1-for-4.5 reverse stock split of its common stock. See Reverse Stock Split below for further information.

Prior to the closing of the Common Stock Offering, the warrants described above were originally recorded as equity at the fair value on the date of issuance. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the Waived Warrants were required to be liability classified immediately after the closing of the Common Stock Offering on June 3, 2013 because there were an insufficient number of common shares authorized to permit the full exercise of the warrants. Therefore on June 3, 2013, the Company reclassified the fair value of the Waived Warrants totaling approximately \$9.1 million from equity to a liability. The Waived Warrants were required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings until such time as there were a sufficient number of common shares authorized to permit the full exercise of the warrants (see Note 11). In connection with the Reverse Stock Split as more fully described below, these warrants were valued as of October 28, 2013, and the Company reclassified the fair value of the Waived Warrants totaling approximately \$5.3 million from a liability to equity.

Following is a summary list of the Waived Warrants:

Shares of common stock associated with the Waived Warrants	Expiration Date of Waived Warrants	Strike Price	Per Share	Per Share
			Fair Value on June 3, 2013	Fair Value on October 28, 2013
1,323,496	2/26/2018	\$5.31	\$ 6.60	\$ 3.86
31,243	7/25/2016	\$18.99	\$ 4.41	\$ 2.10
12,628	7/6/2016	\$14.09	\$ 4.81	\$ 2.40
31,448	11/25/2017	\$12.47	\$ 5.56	\$ 3.16

Assumptions used in the valuation of the Waived Warrants associated with the June 3, 2013 Common Stock Offering are as follows:

	June 3, 2013			October 28, 2013		
Risk-free interest rate	0.50	-	1.03%	0.59	-	1.31%
Expected volatility	102.9	-	110.9%	105.1	-	111.8%
Expected life (in years)	3.1	-	4.7%	2.7	-	4.3%
Expected forfeiture rate			0.0%			0.0%

Expected dividend yield	0.00%	0.00%
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### Reverse Stock Split

On October 28, 2013, the Company effected a 1-for-4.5 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on October 29, 2013. As of that date, each 9 shares of issued and outstanding common stock and equivalents will be consolidated into 2 shares of common stock. In addition, at the market open on October 29, 2013, the Company's common stock started trading under a new CUSIP number 15117N404 although the Company's ticker symbol, CLSN, remained unchanged.

The reverse stock split was previously approved by the Company's stockholders at the 2013 Annual Meeting held on July 19, 2013, and the Company subsequently filed a Certificate of Amendment to its Certificate of Incorporation to effect the stock consolidation. The primary reasons for the reverse stock split and the amendment are:

To increase the market price of the Company's common stock making it more attractive to a broader range of institutional and other investors,

To provide the Company with additional capital resources and flexibility sufficient to execute its business plans including the establishment of strategic relationships with other companies and to ensure its ability to raise additional capital as necessary, and

As previously announced, to facilitate expanding the Company's business or product lines through potential acquisitions.

Immediately prior to the reverse stock split, the Company had 61,226,873 shares of common stock outstanding which consolidated into 13,604,975 shares of the Company's common stock. No fractional shares were issued in connection with the reverse stock split. Holders of fractional shares have been paid out in cash for the fractional portion with the Company's overall exposure for such payouts consisting of a nominal amount. The number of outstanding options and warrants were adjusted accordingly, with outstanding options being reduced from approximately 3.9 million to approximately 0.9 million and outstanding warrants being reduced from approximately 13.8 million to approximately 3.1 million.

January 2011 Preferred Stock Offering

The Company has reassessed the application of ASC 470-20, *Debt with Conversion and Other Options* as it relates to the 8% Series A Redeemable Convertible Preferred Stock Offering completed in January 2011 (the January 2011 Preferred Offering). The Company received gross proceeds from the January 2011 Preferred Offering of approximately \$5.1 million in which it sold 5,000 shares of 8% redeemable convertible preferred stock with a stated value of \$1,000 per share, each share convertible into 92.5926 shares of common stock, and warrants to purchase up to approximately 463,000 shares of common stock. All 5,000 shares of preferred stock sold in the January 2011 Preferred Offering were subsequently converted into the stated number of common stock shares as of August 2011. ASC 470-20 requires the Company to value the preferred stock and common stock warrants, any resulting beneficial conversion feature(s) resulting from the valuation of these securities and to determine and record the value of each of these securities or conversion feature as debt or equity based on the interpretation and application of ASC 470-20.

The Company allocated the proceeds of the Offering between the redeemable preferred stock and the warrants based on fair value and correctly recorded the redeemable preferred stock as a liability (debt), but did not consider the embedded beneficial conversion feature (BCF) associated with the redeemable preferred stock. ASC 470-20 required the Company to record a BCF of approximately \$5 million at the time of issuance of the \$5 million convertible Preferred Stock offering and to amortize the BCF as non-cash interest expense over the conversion period. Since all 462,960 shares were converted by August 8, 2011, the entire \$5 million of BCF should have been amortized as interest expense during 2011. As a result, the Company's interest expense and net loss were understated by \$5 million. The error had no effect on cash, cash flows or total shareholders' equity during 2011 and had no effect on cash, cash flows, net income or total shareholders' equity for any subsequent periods. After considering the quantitative and qualitative effects of the errors to the 2011 annual financial statements, as well as the quarterly period financial statements within 2011, in the opinion of management the error is not material to assessing the financial condition or operations of the Company. The Company has adjusted additional paid-in capital and a corresponding offset to retained earnings on the December 31, 2013 and 2012 balance sheets to reflect this adjustment.

June 2, 2011 Private Placement Offering

On June 2, 2011, the Company completed the issuance and sale in a private placement transaction with institutional investors, as well as certain officers and directors of the Company, of 715,247 shares of common stock and warrants to purchase up to 715,247 shares of the Company's common stock. The common stock and warrants in the June 2, 2011 private placement offering were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. The units sold to unaffiliated institutional investors were sold at a negotiated purchase price of \$12.465 per unit and to officers and directors at \$13.0275 per unit, the latter representing the consolidated closing bid price per share of Company's common stock plus a warrant premium of \$0.5625 per unit. The warrants in this offering were immediately exercisable and have a term of exercise of seventy-eight months from the date of issuance and an exercise price of \$12.47 per share. The Company received gross proceeds from the offering of approximately \$8.6 million before deducting estimated offering expenses.

Concurrent with the issuance and sale of the units of common stock and warrants in this offering, the Company also entered into a registration rights agreement with the investors that required the Company to file a resale registration statement with the Securities and Exchange Commission covering the resale by the investors in this offering of the common stock and the shares of common stock issuable upon exercise of the warrants. These units were filed pursuant to Rule 424(b)(3) under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333-174960 and was declared effective on June 24, 2011.

#### July 6, 2011 Registered Direct Offering

On July 6, 2011, the Company completed the issuance and sale in a registered offering of 715,247 shares of our common stock and warrants to purchase up to 139,704 shares of our common stock to institutional investors. The securities were sold in units at a price of \$14.25375 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.3 shares of common stock, for an aggregate offering price of \$6,637,688 (the "Offering"). Net proceeds from the offering were approximately \$6 million.

Each warrant to purchase shares of common stock in this offering will have an exercise price of \$14.085 per share, for total potential additional proceeds to the Company of up to approximately \$2 million upon exercise of these warrants. These warrants are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance.

The offer and sale of the common stock and warrants (and the shares of common stock issuable upon exercise of the warrants) in this offering are registered under the Securities Act of 1933 (the “Securities Act”), as amended, on a registration statement on Form S-3 (File No. 333-158402).

#### July 25, 2011 Registered Direct and Private Placement Offerings

On July 25, 2011, the Company completed a registered offering of 677,263 shares of its common stock and warrants (the “RD Warrants”) to purchase up to 203,179 shares of its common stock. The common stock and the warrants were sold in units at a price of \$19.159 per unit, with each unit consisting of one share of the Company’s common stock and a warrant to purchase 0.30 shares of the Company’s common stock, for an aggregate registered offering price of \$12,975,506 (the “Registered Offering”).

The offer and sale of the Company’s common stock issued in the Registered Offering and the shares of common stock issuable upon exercise of the warrants issued in the Registered Offering are registered under the Securities Act of 1933, as amended (the “Securities Act”), on a registration statement on Form S-3 (File No. 333-158402), as supplemented and amended by the prospectus supplement filed with the Securities and Exchange Commission on July 25, 2011.

On July 20, 2011, the Company entered into a Purchase Agreement (the “Private Placement Purchase Agreement” and, together with the Registered Direct Purchase Agreement, the “Agreements”) under which the Company agreed to enter into a private placement with other accredited institutional investors, a member of the Company’s Board of Directors, and an accredited institutional investor affiliated another member of the Company’s Board of Directors (collectively, the “Private Offering Purchasers”). Pursuant to the Private Placement Purchase Agreement, the Company issued 284,674 shares of its common stock and warrants (the “Private Placement Warrants”) to purchase up to 113,869 shares of its common stock. The Private Placement Purchase Agreement provided that the securities will be sold in units at a price of \$19,215 per unit, with each unit consisting of one share of the Company’s common stock and a warrant to purchase 0.40 shares of the Company’s common stock, for an aggregate private offering price of \$5,469,998 (the “Private Offering,” collectively with the Registered Offering, the “Offerings”).

In the Offerings, each warrant to purchase shares of the Company’s common stock will have an exercise price of \$18.99 per share, for total potential additional proceeds to the Company of up to approximately \$6 million upon exercise of the warrants. The warrants in the Offerings are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance.

Concurrent with the issuance and sale of the Private Offering common stock and warrants, the Company also entered into a Registration Rights Agreement with the Private Offering Purchasers (the “Registration Rights Agreement”) that

requires the Company to file a registration statement within 30 days of the closing date on July 25, 2011 with the Securities and Exchange Commission covering the resale by the Private Offering Purchasers of the common stock issued in the Private Offering and the shares of common stock issuable upon exercise of the warrants issued in the Private Offering. These Units were filed pursuant to Rule 424(b)(3) under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333-176486 and was declared effective on September 22, 2011.

The purchase and issuance of securities in the Offerings were completed on July 25, 2011. Net proceeds from the Registered Offering and the Private Placement Offering aggregated approximately \$17 million.

#### December 6, 2011 Private Placement Offering

On December 6, 2011, the Company completed the issuance and sale in a private placement transaction with institutional investors, as well as certain directors of the Company, of 1,441,442 shares of common stock and warrants to purchase up to 720,721 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a half of a warrant to purchase one share of common stock. Units sold to unaffiliated institutional investors were sold at a negotiated purchase price of \$10.406 per unit representing the consolidated closing bid price per share of common stock plus a warrant premium of \$0.125 per unit. The Company received gross proceeds from the offering of approximately \$15.0 million before deducting estimated offering expenses.



In this offering, each warrant to purchase shares of the Company's common stock will have an exercise price of \$10.62 per share, for total potential additional proceeds to the Company of up to approximately \$7.7 million upon exercise of the warrants. The warrants in the Offering are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance.

Concurrent with the issuance and sale of the Offering common stock and warrants, the Company also entered into a Registration Rights Agreement with the Purchasers (the "Registration Rights Agreement") that requires the Company to file a registration statement with the Securities and Exchange Commission covering the resale by the Purchasers of the common stock issued in the Offering and the shares of common stock issuable upon exercise of the warrants issued in the Offering. These units were filed pursuant to Rule 424(b)(3) under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333- 178679 and was declared effective on February 8, 2012.

#### Committed Equity Financing Facility (CEFF)

On June 17, 2010, we entered into a Committed Equity Financing Facility (CEFF) with Small Cap Biotech Value Ltd. (SCBV). The CEFF provides that, upon the terms and subject to the conditions set forth therein, SCBV committed to purchase up to \$15.0 million worth of our shares of common stock over the 24-month term of the CEFF under certain specified conditions and limitations, provided that in no event may we sell under the CEFF more than 534,319 shares of common stock, which is equal to one share less than 20% of our outstanding shares of common stock on June 17, 2010, the closing date of the CEFF, less the number of shares of common stock we issued to SCBV on the closing date as Commitment Shares (described below). Furthermore, in no event shall SCBV purchase any shares of our common stock which, when aggregated with all other shares of our common stock then beneficially owned by SCBV, would result in the beneficial ownership by SCBV of more than 9.9% of the then outstanding shares of our common stock. These maximum share and beneficial ownership limitations may not be waived by the parties.

In partial consideration for SCBV's execution and delivery of the CEFF, we issued to SCBV 8,888 shares of our common stock (the "Commitment Shares"). The issuance of the Commitment Shares, together with all other shares of common stock issuable to SCBV pursuant to the terms of the CEFF, is exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) and Regulation D under the Securities Act.

During 2011, the Company completed the three draws and sales of 297,892 shares of the Company's common stock to SCBV under the CEFF resulting in approximately \$3.4 million in gross proceeds.

In connection with the CEFF, the Company capitalized and deferred approximately \$332,000 of fees and expenses in 2010. A portion of these amounts were amortized each time the Company completed a draw under the CEFF. During

2011, \$274,806 of these expenses was amortized in connection with the three draws in 2011.

The proceeds from the CEFF draws were used for general corporate purposes, including the funding of the Company's clinical development pipeline of cancer drugs. SCBV is an accredited investor as such term is defined in Rule 501 of Regulation D of the Securities Act of 1933, as amended (the "Securities Act"), and all sales of the Company's common stock to SCBV pursuant to the CEFF were exempt from registration pursuant to Section 4(2) of the Securities Act and Rule 506 of Regulation D of the Securities Act. The Company has registered the resale of the shares of common stock issued to SCBV pursuant to the CEFF under the Securities Act on a registration statement on Form S-1.

Availability under the CEFF was exhausted during the second quarter of 2011. Also, in connection with equity offerings in the second quarter of 2011, the Company agreed to suspend the use of the CEFF and expensed the unamortized deferred financing fees of \$274,806 in the 2011.

## **10. STOCK BASED COMPENSATION**

### Employee Stock Options

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. Generally, the terms of these plans require that the exercise price of the options may not be less than the fair market value of Celsion's Common Stock on the date the options are granted. Options generally vest over various time frames or upon milestone accomplishments. Some vest immediately. Others vest over a period between one and five years. The options generally expire ten years from the date of the grant.

### *2001 Stock Option Plan*

In 2001, the Board of Directors adopted a stock plan for directors, officers and employees (the “2001 Plan”) under which 148,148 shares were reserved for future issuance. The purpose of the 2001 Plan was to promote long-term growth and profitability of Celsion by providing key people with incentives to improve stockholder value and contribute to the growth and financial success of Celsion, and to enable the company to attract, retain and reward the best available persons for positions of substantial responsibility.

### *2004 Stock Incentive Plan*

In 2004, the Board of Directors adopted a stock plan for directors, officers and employees (the “2004 Plan”) under which 148,148 shares were reserved for future issuance. The plan provides for stock instruments to be issued enabling the holder thereof to acquire Common stock of the Company at prices determined by the Company’s Board of Directors. The purpose of the 2004 Plan was to promote the long-term growth and financial success of the Company and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2004 Plan permitted the granting of awards in the form of incentive stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. The 2004 Plan terminates in 2014, 10 years from the date of the Plan’s adoption by the Company’s stockholders.

Any options forfeited or terminated under the 2001 Plan and 2004 Plan are rolled into the 2007 Stock Incentive Plan for future issuance.

### *2007 Stock Incentive Plan*

On June 13, 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the “2007 Plan”) under which 222,222 shares was available for issuance. The purpose of the 2007 Plan is to promote the long-term growth and profitability of the Company by providing incentives to improve stockholder value and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2007 Plan permits the granting of awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. At the Annual Meetings of Stockholders of Celsion held on June 25, 2010 and June 7, 2012, the stockholders approved amendments to the Plan. The only material difference between the existing Plan and the amended Plan was the number of shares of common stock available for issuance under the amended Plan which was increased by 222,222 to a total of 444,444 shares in 2010 and by 500,000 to a total of 944,444 shares in 2012.

The Company has issued stock options and warrants to employees, directors, vendors and debt holders. Options and warrants are generally granted at market value on the date of the grant.

Incentive stock options may be granted to purchase shares of Common Stock at a price not less than 100% of the fair market value of the underlying shares on the date of grant, provided that the exercise price of any incentive option granted to an eligible employee owning more than 10% of the outstanding stock must be at least 110% of the such fair market value on the date of grant. Only officers and key employees may receive incentive stock options; all other qualified participants may receive non-qualified stock options.

Option awards vest upon terms determined by the Board of Directors. Restricted stock awards, performance stock awards and stock options are subject to accelerated vesting in the event of a change of control. The Company issues new shares to satisfy its obligations from the exercise of options.

During the year ended December 31, 2013, 2012 and 2011, 187,888, 148,553 and 277,036 equity awards, respectively, were granted under the 2007 Plan. During 2013, 2012 and 2011, a total of 41,379, 66,019 and 57,000 equity awards, respectively, were canceled or expired under the plans collectively. During 2013, 2012 and 2011, 12,873, 56,710 and 14,933 shares of the Company's common stock were issued collectively as a result of either options being exercised or restricted stock awards vesting.

In 2007 an option to purchase 95,555 shares of the Company's common stock was issued to the Company's Chief Executive Officer. This option vested in equal installments over four years and was separately registered with the Securities and Exchange Commission (the "SEC") and was not issued under any of the Employee Stock Incentive Plans.

As of December 31, 2013, there were a total of 863,461 shares reserved and there were a total of 332,151 shares available for future issuance under the option plans and incentive awards collectively.

Total compensation cost charged related to employee stock options and non-vested restricted stock awards amounted to 1.2 million, \$1.1 million and \$1.2 million for the years ended December 31, 2013, 2012 and 2011, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset at these same periods.

As of December 31, 2013, there was \$1.2 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.3 years. The weighted average grant-date fair values of the equity awards granted during the years ended December 31, 2013, 2012 and 2011 were \$3.40, \$7.28 and \$8.48, respectively.

Equity Awards Issued to Consultants for Services

The Company periodically issues equity awards to consultants in exchange for services provided. The fair value of options granted is measured in accordance with ASC 718, *Compensation – Stock Compensation*, using the Black-Scholes option pricing model and recorded as an expense in the period in which such services are received. Generally, the terms of these plans require that the exercise price of such awards may not be less than the fair market value of the Company’s Common Stock on the date the equity awards are granted. Consultant equity awards generally vest over various time frames or upon milestone accomplishments. Some vest immediately upon issuance. The equity awards generally expire within 10 years from the date of grant. There were 5,555, 5,387 and 5,000 awards issued to consultants during the years ended December 31, 2013, 2012 and 2011, respectively.

A summary of stock option awards as of December 31, 2013 and changes during the three years ended December 31, 2013, is presented below:

<b>Stock Options</b>	<b>Number</b>	<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate</b>
	<b>Outstanding</b>	<b>Average</b>	<b>Average</b>	<b>Intrinsic</b>
		<b>Exercise</b>	<b>Remaining</b>	<b>Value</b>
		<b>Price</b>	<b>Contractual</b>	
			<b>Term</b>	

**(in years)**

Outstanding at January 1, 2011	481,699	\$ 17.82		
Granted	265,703	16.52		
Exercised	—	—		
Canceled or expired	(55,593 )	14.54		
Outstanding at December 31, 2011	691,809	16.88		
Granted	145,611	10.08		
Exercised	(47,575 )	14.67		
Canceled or expired	(64,316 )	29.43		
Outstanding at December 31, 2012	725,529	14.63		
Granted	187,777	4.39		
Exercised	(12,429 )	14.67		
Canceled or expired	(38,972 )	16.79		
Outstanding at December 31, 2013	861,905	\$ 12.29	6.6	\$ -
Exercisable at December 31, 2013	601,482	\$ 14.28	6.3	\$ -

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A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2013 and changes during the two years ended December 31, 2013, is presented below:

<b>Restricted Stock</b>	<b>Number</b>		<b>Weighted</b>	
			<b>Average</b>	<b>Exercise</b>
	<b>Outstanding</b>			<b>Price</b>
Outstanding at January 1, 2011	17,200			\$ 15.62
Granted	11,333			12.29
Vested and issued	(14,933)	)		14.04
Forfeited	(1,407)	)		17.82
Non-vested stock awards outstanding at December 31, 2011	12,193			\$ 14.22
Granted	2,942			16.47
Vested and issued	(9,135)	)		15.17
Forfeited	(1,703)	)		12.56
Non-vested stock awards outstanding at December 31, 2012	4,294			\$ 14.63
Granted	111			5.36
Vested and issued	(444)	)		8.40
Forfeited	(2,407)	)		15.69
Non-vested stock awards outstanding at December 31, 2013	1,557			\$ 14.13

A summary of stock options outstanding at December 31, 2013 by price range is as follows:

<b>Range of Exercise Prices</b>	<b>Options Outstanding</b>			<b>Options Exercisable</b>		
	<b>Number</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Weighted Average Exercise Price</b>	<b>Number</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Weighted Average Exercise Price</b>
\$ 0.50 - \$8.99	189,630	9.3	\$ 4.46	62,513	9.3	\$ 4.46
\$ 9.00 - \$13.50	477,553	6.1	\$ 11.12	356,524	5.4	\$ 11.43
\$ 13.51 - \$30.00	183,620	4.2	\$ 21.33	171,343	4.0	\$ 21.67
Above \$30.00	11,102	0.9	\$ 57.29	11,102	0.9	\$ 57.29
	861,905			601,482		

The fair values of stock options granted were estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes model was originally developed for use in estimating the fair value of traded options, which have different characteristics from Celsion's nonqualified stock options. The model is also sensitive to changes in assumptions, which can materially affect the fair value estimate. The Company used the following assumptions for determining the fair value of options granted under the Black-Scholes option pricing model:

	<b>Year Ended December 31,</b>					
	<b>2013</b>		<b>2012</b>		<b>2011</b>	
Risk-free interest rate	0.85to	1.19%	1.09to	2.97%	2.29to	2.97%
Expected volatility	83.4-	97.9%	80.8-	82.3%	72.2-	81.0%
Expected life (in years)	5.25to	6.00	5.00to	6.25	6.25	
Expected forfeiture rate	5.0 to	7.5%	7.5%		0.0%	
Expected dividend yield	0.0%		0.0%		0.0%	

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. The risk free interest rate is derived from values assigned to U.S. Treasury strips as published in the Wall Street Journal in effect at the time of grant. The model incorporates exercise, pre-vesting and post-vesting forfeiture assumptions based on analysis of historical data. The expected life of the fiscal 2013, 2012 and 2011 grants was generated using the simplified method as allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107.



**11. WARRANTS**

As more fully described in Note 9, the Company completed a series of equity financing transactions in 2013 and 2011 that included the issuance of warrants to purchase 1,341,382 and 2,394,398 shares, respectively, of the Company's common stock. In connection with the Hercules Credit Agreement and the Horizon & Oxford Credit Agreement the Company entered into in November 2013 and June 2012 as more fully described in Note 7, the Company issued warrants to purchase 194,986 and 11,415 shares, respectively, of the Company's common stock. During 2013, 2012 and 2011, the Company received gross proceeds of approximately \$0.2 million, \$10.2 million and \$0.4 million, respectively, from the exercise of warrants to purchase 15,833, 847,715 and 34,859 shares of common stock, respectively.

Following is a summary of all warrant activity for the three years ended December 31, 2012:

<b>Warrants</b>	<b>Number of Warrants Issued</b>	<b>Weighted Average Exercise Price</b>
Warrants outstanding at January 1, 2011	224,239	\$ 23.58
Warrants issued in connection with 2011 equity transactions	2,394,398	13.28
Warrants exercised for common stock warrants in 2011	(34,859 )	12.29
Warrants outstanding at December 31, 2011	2,583,778	\$ 14.18
Warrants issued in connection with the Oxford & Horizon Credit Agreement as more fully described in Note 7	11,415	\$ 13.14
Warrants exercised for common stock in 2012	(847,715 )	12.11
Warrants outstanding at December 31, 2012	1,747,478	15.17
Warrants issued in connection with 2013 equity transactions	1,341,382	5.31
Warrants issued in connection with the Hercules Credit Agreement as more fully described in Note 7	194,986	3.59
Warrants exercised for common stock in 2013	(15,833 )	14.63
	3,268,013	\$ 10.43
Aggregate intrinsic value of outstanding warrants at December 31, 2013		\$58,496
Weighted average remaining contractual terms (years)		3.56

Common Stock Warrant Liability

In September 2009, the Company closed a registered direct offering with a select group of institutional investors that raised gross proceeds of \$7.1 million and net proceeds of \$6.3 million. In connection with this registered direct offering, the Company issued 484,478 shares of its common stock and warrants to purchase 224,239 shares of common stock. The warrants have an exercise price of \$23.58 per share and are exercisable at any time on or after the six month anniversary of the date of issuance and on or prior to 66 months after the date of issuance. Under the terms of the warrants, upon certain transactions, including a merger, tender offer or sale of all or substantially all of the assets of the Company, each warrant holder may elect to receive a cash payment in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model. Accordingly, pursuant to ASC 815.40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the warrants are recorded as a liability and then marked to market each period through the Statement of Operations in other income or expense. At the end of each subsequent quarter, the Company will revalue the fair value of the warrants and the change in fair value will be recorded as a change to the warrant liability and the difference will be recorded through the Statement of Operations in other income or expense.

As more fully described in Note 9, concurrent with the closing of the Common Stock Offering, the investors in this offering agreed to waive their rights to exercise the Waived Warrants to purchase 1,398,816 shares of common stock of the Company until the Company has obtained stockholders' approval of increasing the number of its authorized shares of common stock in conjunction with the proposed reverse stock split of its outstanding shares of common stock. In accordance with ASC 815-40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the Waived Warrants were required to be classified as liabilities immediately after the closing of the Common Stock Offering on June 3, 2013 because there were an insufficient number of common shares authorized to permit the full exercise of the Waived Warrants if they were exercised. Therefore, the Company had reclassified the fair value of the Waived Warrants totaling approximately \$9.1 million from equity to a liability as of June 3, 2013. The Waived Warrants were required to be recorded at fair value at each balance sheet date with changes in fair value recorded in earnings until such time as there are a sufficient number of common shares authorized to permit the full exercise of the warrants. In connection with the Reverse Stock Split, these warrants were valued as of October 28, 2013 and the Company reclassified the fair value of the Waived Warrants totaling approximately \$5.3 million from a liability to equity.

As of December 31, 2013 and 2012, the Company recorded a common stock warrant liability of \$3,026 and \$4.3 million respectively. The fair value of the warrants associated with the September 2009 registered direct offering at December 31, 2013, 2012 and 2011 was calculated using the Black-Scholes option-pricing model with the following assumptions:

	<b>December 31,</b>					
	<b>2013</b>		<b>2012</b>		<b>2011</b>	
Risk-free interest rate	0.13	%	0.73	%	0.83	%
Expected volatility	64.74	%	92.02	%	75.17	%
Expected life (in years)	1.25		1.13		1.6	
Expected forfeiture rate	0.0	%	0.0	%	0.0	%
Expected dividend yield	0.00	%	0.00	%	0.00	%

See Note 9 for the assumptions used at June 3, 2013 and October 28, 2013 for the Black-Scholes option-pricing model calculation for the Waived Warrants associated with the Common Stock Offering on the dates they were waived and when there became a sufficient number of common shares authorized to permit their full exercise.

As a result of this change in the warrant liability in 2013, which included the change in the warrant liability associated with the Waived Warrants as discussed above, the Company recorded a non-cash benefit of \$8.1 million during 2013. The change in the warrant liability during 2012 and 2011 resulted in a non-cash loss of \$4.1 million in 2012 and a non-cash benefit of \$0.1 million in 2011. The following is a summary of the changes in the common stock warrant liability for 2013, 2012 and 2011:

Beginning balance, January 1, 2011	\$248,131
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Benefit from the adjustment for the change in fair value included in net loss for 2010	(81,733 )
Balance at December 31, 2011	166,398
Benefit from the adjustment for the change in fair value included in net loss for 2011	4,117,534 )
Balance at December 31, 2012	4,283,932
Fair value of warrants classified as liability (see Note 9)	9,110,302
Fair value of warrants classified as equity (see Note 9)	(5,300,572)
Gain from the adjustment for the change in fair value included in net loss	(8,090,636)
Ending balance, December 31, 2013	\$3,026

## 12. CELSION EMPLOYEE BENEFIT PLANS

Celsion maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees over the age of 21. Participating employees may defer a portion of their pretax earnings, up to the IRS annual contribution limit. Commencing in the fourth quarter for 2008, the Company began making a matching contribution up to a maximum of 3% of an employee's annual salary and the Company's total contribution for the years ended December 31, 2013, 2012 and 2011 was \$62,546, \$57,239 and \$60,360 respectively. The Company's contribution was made in the form of our common stock.

### 13. LICENSES OF INTELLECTUAL PROPERTY AND PATENTS

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received worldwide exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermally sensitive liposome technology. The license agreement contains annual royalty and minimum payment provisions due on net sales. The agreement also required milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke agreed to accept shares of the Company's Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance.

The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement. On January 31, 2003, the Company issued 253,691 shares of Common Stock to Duke University valued at \$2.2 million as payment for milestone based royalties under this license agreement. An amendment to the Duke license agreement contains certain development and regulatory milestones, and other performance requirements that the Company has met with respect to the use of the licensed technologies. The Company will be obligated to make royalty payments based on sales to Duke upon commercialization, until the last of the Duke patents expire.

For the years ended December 31, 2013, 2012 and 2011, the Company has not incurred any expense under this agreement and will not incur any future liabilities until commercial sales commence.

Under the November 1999 license agreement with Duke, the Company has rights to the thermally sensitive liposome technology, including Duke's US patents covering the technology as well as all foreign counterpart parts and related pending applications. Foreign counterpart applications have been issued in Europe, Hong Kong, Australia and Canada and have been allowed in Japan. The Japanese allowed application is expected to issue without hindrance in March of 2011. The European patent has been validated in Austria, Belgium, France, Germany, Great Britain, Italy, Luxembourg, Monaco, Spain and Switzerland. In addition, the Duke license agreement provides the Company with rights to multiple issued and pending US patents related to the formulation, method of making and use of heat sensitive liposomes. The Company's rights under the license agreement with Duke University extend for the life of the last-to-expire of the licensed patents.

The Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In addition to the rights available to the Company under completed or pending license agreements, the Company is actively pursuing patent protection for technologies developed by the Company. Among these patents is a family of pending US and international patent applications which seek to protect the Company's proprietary method of storing ThermoDox® which is critical for worldwide distribution channels.

ThermoDox® is a registered trademark in the United States, Argentina, Australia, Canada, China, Columbia, the European Communities: (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Korea, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK), Hong Kong, Israel, Japan, New Zealand, Peru, Philippines, Russia, Singapore, South Korea and Taiwan. The Company has registered transliterations of ThermoDox® in China, Hong Kong, Japan, Singapore, South Korea and Taiwan. The Company has an additional 14 trademark protection applications pending for ThermoDox® in countries world-wide.

Finally, through proprietary information agreements with employees, consultants and others, the Company seeks to protect its own proprietary know-how and trade secrets. The Company cannot offer assurances that these confidentiality agreements will not be breached, that the Company will have adequate remedies for any breach, or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company's proprietary technology. Similarly, the Company cannot guarantee that technology rights licensed to it by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide the Company with adequate protection.

#### 14. TECHNOLOGY DEVELOPMENT AND LICENSING AGREEMENTS

On May 7, 2012 the Company entered into a long term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in the China territory. In accordance with the terms of the agreement, Hisun will be responsible for providing all of the technical and regulatory support services, including the costs of all technical transfer, registration and bioequivalence studies, technical transfer costs, Celsion consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. Celsion will repay Hisun for the aggregate amount of these development costs and fees commencing on the successful completion of three registration batches of ThermoDox®. Hisun is also obligated to certain performance requirements under the agreement. The agreement will initially be limited to a percentage of the production requirements of ThermoDox® in the China territory with Hisun retaining an option for additional global supply after local regulatory approval in the China territory. In addition, Hisun will collaborate with Celsion around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (CHINA FDA). As of September 30, 2013, the Company has incurred approximately \$371,000 in costs to be reimbursed to Hisun.

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5 million to support our development of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Celsion and Hisun have agreed that the Technology Development Contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate and are evaluating the next steps in relation to ThermoDox®, which include the sub-group analysis of patients in the Phase III HEAT Study for the hepatocellular carcinoma clinical indication and other activities to further the development of ThermoDox® for the Greater China market. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will continue to be amortized over the 10 year term of the agreement, until such time as the parties find a mutually acceptable path forward on the development of ThermoDox based on findings of the ongoing post-study analysis of the HEAT Study data.

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

Among the key provisions of the Celsion-Hisun Memorandum of Understanding are:

Hisun will provide the Company with non-dilutive financing and the investment necessary to complete the technology transfer of its proprietary manufacturing process and the production of registration batches for the

China territory;

Hisun will collaborate with the Company around the clinical and regulatory approval activities for ThermoDox® as well as other liposomal formations with the CHINA FDA; and

Hisun will be granted a right of first offer for a commercial license to ThermoDox® for the sale and distribution of ThermoDox® in the China territory.

In the fourth quarter of 2008, the Company entered into a Development, Product Supply and Commercialization Agreement with Yakult Honsha under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and we have the potential to receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. We will receive double digit escalating royalties on the sale ThermoDox® in Japan, when and if any such sales occur. We also will be the exclusive supplier of ThermoDox® to Yakult.

Concurrent with the January 2011 Preferred Equity Financing as discussed in Note 9 to the Financial Statements, the Company amended its Development, Product Supply and Commercialization Agreement with Yakult to provide for up to \$4.0 million in an accelerated partial payment to the Company of a future drug approval milestone, which included \$2.0 million paid to the Company upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study. In consideration of these accelerated milestone payments from Yakult, the Company agreed to reduce future drug approval milestone payments by approximately forty percent (40%).



## 15. CONTINGENT LIABILITIES AND COMMITMENTS

In July 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for 6 months rent free, with the first monthly rent payment of approximately \$23,000 due and paid in April 2012. Also, as required by the Lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the Lease Term has expired. In connection with the \$50,000 reduction of the standby letter of credit in April 2013, the Company reduced the escrow deposit by \$50,000.

Following is a summary of the future minimum payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2013:

	<b>Capital</b>	<b>Operating</b>
For the year ending December 31:	<b>Leases</b>	<b>Leases</b>
2014	\$ 11,303	\$ 286,243
2015	—	291,678
2016	—	297,113
2017	—	99,642
2018 and beyond	—	—
Total minimum lease payments	11,303	\$ 974,676
Less amounts of lease payments that represent interest	412	
Present value of future minimum capital lease payments	10,891	
Less current obligations under capital leases	10,891	
	\$—	

## 16. SUBSEQUENT EVENTS

On January 15, 2014, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which Celsion agreed to sell, in a registered offering, an aggregate of 3,603,604 shares of its common stock, par value \$0.01 per share, and warrants to purchase up to 1,801,802 shares of Common Stock, for an aggregate purchase price of approximately \$15 million. The shares of common stock and warrants were sold in units, with each unit consisting of one share of common stock, a Series A warrant to purchase 0.25 share of common stock and a

Series B warrant to purchase 0.25 share of common stock. Each unit was sold at a purchase price of \$4.1625. Each Series A warrant will be exercisable at any time on or after its issuance date and until the five-year anniversary of the issuance date. Each Series B warrant will be exercisable at any time on or after its issuance date and until the one-year anniversary of the issuance date. Each warrant has an exercise price of \$4.10 per share. Under the purchase agreement, Celsion is prohibited, for a period of nine months after the closing, from effecting or entering into an agreement to issue Common Stock or any other securities that are at any time convertible into, or exercisable or exchangeable for, or otherwise entitle the holder thereof to receive, Common Stock to the extent such issuance or sale involves certain variable conversion, exercise or exchange prices or such agreement provides for sale of securities at a price to be determined in the future. This offering was made pursuant to the Company's previously filed and effective registration statement on Form S-3 (File No. 333-183286), the base prospectus dated September 14, 2012 filed as part of such registration statement, and the prospectus supplement filed by Celsion with the Securities and Exchange Commission on January 21, 2014.

**17. SELECTED QUARTERLY FINANCIAL DATA (Unaudited)****(in thousands, except per share data)**

	<b>Quarters Ended</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>2013</b>				
Total revenue	\$ 125	\$ 125	\$ 125	\$ 125
Net loss	(651 )	421	(4,072 )	(3,949 )
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	(4,601)			
Basic and diluted net loss available to common shareholders per share	(0.48 )	0.03	(0.30 )	(0.29 )
<b>2012</b>				
Total revenue	\$	\$	\$	\$
Net loss	(6,186)	(6,104)	(6,018 )	(8,260 )
Basic and diluted net loss per share	(0.19 )	(0.18 )	(0.18 )	(0.23 )

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